



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:) Art Unit: 1761
)
Dov Hartal et al) Examiner: C.E. Sherrer
)
Appln. No.: 09/449,093) Washington, D.C.
)
Date Filed: November 24, 1999) December 29, 2003
)
For: NATURAL COLORING PRODUCTS) Confirmation No.: 5856
)
) ATTY.'S DOCKET: HARTAL=1B

BRIEF ON BEHALF OF APPELLANTS

Customer Window, Mail Stop APPEAL BRIEF-PATENTS
Honorable Commissioner for Patents
Arlington, VA 22202

Sir:

The present Appeal is taken from the Action of the examiner in finally rejecting claims 1-14, 23-38 and 41-45. A clean copy of these claims, double spaced, appears in the Appendix to this Brief.

REAL PARTY IN INTEREST

The real party in interest is Lycored Natural Products Industries, Ltd. which is a subsidiary of Makhteshim-Agan Industries Ltd.

RELATED APPEALS AND INTERFERENCES

Undersigned is aware of no related appeals or interferences.

STATUS OF THE CLAIMS

All the claims are rejected.

STATUS OF AMENDMENTS

All amendments have been entered.

SUMMARY OF INVENTION

The present invention relates to a concentrated lycopene product (specification page 1, second paragraph¹; page 9, second paragraph) in which the lycopene is largely protected from oxidation by the chromoplast shells or capsules which surround the lycopene, a small fraction of which are broken (page 6, last paragraph; page 7, lines 10-12). Because of the retention of the chromoplasts capsule or shell, with the lycopene therewithin, color intensity is maintained due to decreased oxidation of the lycopene, whereby the concentrated lycopene product of the present invention is a highly desirable red coloring material for food and other products (page 1, second paragraph; page 5, second through fourth paragraphs), as well as a neutraceutical (page 6, third and last paragraphs).

A problem which has existed in the prior art with attempts to provide coloring materials in the yellow-red color range from natural sources, which are not suspected of being harmful to health, is the fact that (1) the coloring potency of such materials is usually inferior to that of synthetic colorants, and (2) such natural coloring materials tend to change their color as a result of pH changes or due to oxidation, and "are often readily destroyed by [only] moderate heat." Heating is therefore disadvantageous, and the problem with conventionally extracted lycopene is that its exposure to oxygen, particularly under the effects of even only moderate heat, causes the lycopene to lose its bright red color (page 1, fourth paragraph).

A problem which therefore faced the Appellants was how to prevent color change, especially due to oxidation, and how to provide a high coloring potency by the use of lycopene, bearing in mind that conventional methods of extraction of lycopene from plant sources, particularly tomatoes, tends to destroy the crystalline structure of the lycopene pigment, thus altering its red color to orange-yellow, similar to the color obtainable with beta-carotene (page 2, lines 2-6).

It is of course known to produce tomato products rich in lycopene, e.g. tomato sauce, tomato paste, tomato

¹ Unless otherwise indicated references hereinafter are to Appellants' specification.

juice, etc., as acknowledged in the middle paragraph on page 4 of Appellants' specification:

Many processes are also known in the art for producing tomato pastes and concentrates, products which do indeed contain high concentrations of lycopene. However, these products also contain high concentrations of those tomato components which contribute aroma, viscosity and flavor to the final product. These latter properties are contributed by the soluble solids present in tomato. In the tomato, soluble solids constitute about 5% by weight of the whole fruit. The insoluble solids, which include the lycopene-containing chromoplasts, constitute about 1% of the weight of the fruit, while the remaining 94% is contributed by water. In the production of tomato paste, only water is removed, thus increasing the concentrations of both the soluble and insoluble solids by the same ratio.

Appellants' specification continues in this regard in the bottom paragraph on page 4 as follows:

In the field of food technology, the soluble solids content of foods is frequently reported in degrees Brix, (°Bx) which is a measurement of the light refraction of the dissolved solids, expressed as sucrose. While a native whole tomato contains approximately 5° Bx of soluble solids, commercially available tomato pastes contain about 30° Bx. Similarly, while a native whole tomato typically contains approximately 70 ppm lycopene, commercially available tomato pastes contain approximately 350 to 400 ppm lycopene. Hence, while tomato paste is enriched about 6-fold in lycopene concentration, taking into consideration losses incurred upon processing, tomato paste is also enriched

about 6-fold in the concentration of the components which contribute tomato flavor.

This is basically what the prior art discloses. In addition, the processes of making these conventional tomato products causes destruction of the chromoplast membrane.

The present invention solves the problems inherent in the prior art, especially the problem with conventionally extracted lycopene involving its exposure to oxygen under moderate heat which causes it to lose its bright red color. Thus, from the top of page 7 of Appellants' specification:

Naturally occurring chromoplasts present in fruits are small natural double-membrane capsules. Chromoplasts present in lycopene-rich fruit, such as tomato, contain lycopene in crystalline form, and in varying concentrations and crystal sizes. Upon breakage and fractionation of tomato fruit into soluble and insoluble fractions, the chromoplasts are found in the insoluble fraction in concentrated form. The intense red color of lycopene is absolutely dependent on its intact crystalline structure; hence it is likely that keeping the lycopene associated with the chromoplasts, either intact or partially broken, is instrumental in maintaining the red color. That is, the crystalline structure of lycopene is more readily preserved therein, and is not destroyed or otherwise changed, as occurs with rigorous extraction of the chromoplasts.

A key aspect of the present invention therefor is to liberate the chromoplast from the fruit without causing substantial mechanical breakage or destruction of the chromoplast

membrane. This is summarized at the bottom of page 6 of Appellants' specification as follows:

The coloring material of the invention comprises, as the color-imparting agent, intact and partially broken chromoplast particles containing crystalline lycopene, separated from the fruit which contained them, and from the bulk of the flavor-imparting components of the fruit. Said chromoplast particles containing crystalline lycopene also comprise a neutraceutical, natural lycopene being an effective antioxidant, useful for promoting and maintaining human health.

And at the end of the first paragraph on page 7:

Additionally, the chromoplast particles containing crystalline lycopene, separated from the fruit which contained them, have been found to be relatively insensitive to the effects of heat and oxidation, which strongly and adversely affect pure lycopene.

The present invention effectively achieves the objective of providing a highly concentrated lycopene product having simultaneously a soluble solids concentration below 5° Bx and a high concentration (500-3,000 ppm) of crystalline lycopene mostly encapsulated within the chromoplasts and thereby protected from oxidation, thus providing a bright red coloring material which also is a neutraceutical. From the top paragraph on page 9:

Lycopene in the coloring material of the present invention is in the concentration range from 500 to 3000 ppm, which is at least 10-fold the concentration of lycopene found in whole native tomatoes, which is in the range from 50 to 100 ppm. At the same

time, the concentration of soluble solids in the coloring material of the present invention is no greater than 5° Bx, which is approximately the same concentration of soluble solids found in whole native tomatoes. That is, the red color potency of the coloring material of the present invention is approximately 10-fold that of whole native tomatoes, while the flavor value of the coloring material of the present invention is not at all concentrated.

ISSUES

There are many issues due to the many rejections.²

A first issue is whether or not claims 1-14, 23-28, 44 and 45 meet the "description" requirement of the first paragraph of §112.

A second issue is whether claims 1-14, 23-28 and 41-45 meet the enablement requirement of the first paragraph of §112.

A third issue is whether or not claims 1-14, 23-28 and 41-44 meet the requirements of the second paragraph of §112.

A series of issues exist as to whether or not appellants' claims are anticipated by the disclosures of certain citations as outlined below, and thus properly rejectable under §102:

² Appellants' apologize for the length of this Brief which, however, is necessitated by the prolixity of the rejections. Appellants' submit that such a multiplicity of rejections is contrary to at least the spirit, if not the letter, of MPEP 706.02.

whether or not claims 1-14, 23-25, 28 and 45 are properly anticipated by Graves et al USP 5,245,095 (hereinafter "Graves");

whether or not claims 14 and 41-43 are anticipated by Tonnuci et al, Journal of Agriculture and Food Chemistry (hereinafter simply "Tonnuci");

whether or not claims 1-3 and 5-7 are anticipated by Brumlick et al USP 4,181,743 (hereinafter simply "Brumlick");

whether or not claims 1-3, 5, 6, 13 and 14 are anticipated by Szabo et al USP 3,864,504 (hereinafter simply "Szabo");

whether or not claims 1-5 and 14 are anticipated by Bradley USP 4,670,281 (Bradley);

whether or not claims 1-5, 7, 13 and 14 are anticipated by Lang USP 5,229,160 (Lang).

There are also issues under §103, the main issues under §103 being:

whether or not claims 26 and 27 would have been obvious to a person of ordinary skill in the art at the time appellants' invention was made from a consideration of Graves in view of Horn et al USP 4,726,955 (hereinafter simply "Horn");

whether or not claims 1-5, 7, 13 and 14 would have been obvious from Lang in view of Brumlick; and

whether or not claims 1-14, 24-28 and 45 would have been obvious from Tonnuci in view of Dale et al, Journal of Food Science (hereinafter simply "Dale").

As regards the rejections under §103, there are of course a series of sub-issues as well, including among others whether or not the person of ordinary skill in the art would have attempted to combine the references as proposed; whether or not the references, even if combinable, would have led to the claimed subject matter; and whether or not a consideration of the prior art in combination would have provided any reasonable expectation of appellants' results.

Other sub-issues will become apparent from Appellants' argument section appearing below.

GROUPING OF CLAIMS

First, of course, all the claims that are subject to different rejections must be considered separately. Therefore, for this reason alone, applicants' claims do not all stand or fall together. Other reasons why they do not stand or fall together will be pointed out in the "Argument" section below.

However, for purposes of this appeal, and relative to the rejections based on the first paragraph of §112, claims 2-7 and 23 may be considered along with claim 1, and need not be considered separately; and claims 9-14 and 24-28

may be considered along with claim 8, and need not be considered separately.

As regards the rejection based on the second paragraph, it appears to be directed **only** against claim 5, and it therefore appears that only claim 5 needs to be considered relative to this rejection.

As regards the rejection under §102 based on Graves, the product claims and the method claims should be considered separately. Among the product claims 1-7, 14 and 23, claims 2, 3, 7 and 23 may be considered along with claim 1, and need not be considered separately; but claims 4, 5 and 14 should be considered separately. Among the method claims 8-13, 24, 25, 28 and 45, claims 9, 11 and 12 can be considered along with claim 8 and claims 25 and 28 can be considered along with claim 24; but all of the other claims should be considered separately.

As regards claims 14 and 41-43 which are rejected under §102 as anticipated by Tonnuci, claims 14, 41 and 42 may be considered together, but claim 43 should be considered separately.

As regards claims 1-3 and 5-7 which are rejected under §102 as anticipated by Brumlick, claims 2, 3, 6 and 7 may be considered along with claim 1 and need not be

considered separately, whereas claim 5 should be considered separately.

As regards the rejection under §102 of claims 1-3, 5, 6, 13 and 14 said to be anticipated by Szabo, claims 2, 3 and 6 can be considered along with claim 1 and need not be considered separately. Claims 5, 13 and 14 should be considered separately.

As regards claims 1-5 and 14 rejected under §102 as anticipated by Bradley, again claims 2, 3 and 14 may be considered along with claim 1, but claims 4 and 5 should be considered separately.

As regards claims 1-5, 7, 13 and 14 rejected under §102 as anticipated by Lang, again claims 2 and 3 may be considered along with claim 1 and need not be considered separately. Each of claims 4, 5, 7, 13 and 14 should be considered separately.

As regards the rejection of claims 26 and 27 under §103 as obvious from Graves in view of Horn, these claims may be considered together.

As regards the rejection under §103 of claims 1-5, 7, 13 and 14 as obvious from Lang in view of Brumlick, again claims 2 and 3 may be considered along with claim 1 and need not be considered separately. But claims 4, 5, 7, 13 and 14 should each be considered separately.

As regards the rejection of claims 1-14, 24-28 and 45 as obvious under §103 from Tonnuci in view of Dale, the product claims and the method claims should be considered separately. Among the product claims 1-7 and 14, claims 2, 3, 6 and 7 may be considered along with claim 1, and need not be considered separately; but claims 4, 5 and 14 should be considered separately. Among the method claims 8-13, 24, 25, 28 and 45, claims 9, 11 and 12 may be considered along with claim 8, and claims 25 and 28 can be considered along with claim 24, but the other claims should be considered separately.

Appellants make no admissions that any of the claims are or are not patentably distinct from one another.

THE DECLARATION

Along with the Reply filed June 10, 2003³, Appellants filed a Declaration in the name of the first named inventor and applicant, Dr. Dov Hartal. On August 1, 2003, the same day the final Action was issued, and of course before Appellants' receipt of the final Action, Appellants filed documentary evidence in support of Dr. Hartal's Declaration. The Declaration and supporting documentary evidence was submitted because of the Examiner's refusal to accept allegations of the Appellants, including statements made in

Appellants' specification⁴. Appellants will refer to the Declaration and the supporting documentary evidence at appropriate points in the "Argument" section of this Brief, below.

ARGUMENT

Appellants respectfully submit that Appellants' claims meet all the statutory requirements, including those of §§112, 102 and 103 for patentability, and that the examiner has not met his initial burden as required by MPEP 706.02(j).

I- Appellants' Claims Meet the "Description" Requirement of the First Paragraph of §112

Claim 1 of the present application calls for a coloring material in the red color range which "comprises from 500-3,000 ppm of said chromoplast particles encapsulating crystalline lycopene", the "said chromoplast particles" being recited as "particles separated from a fruit which contained them".

³ The Reply is misdated June 4, 2003.

⁴ Appellants wish to respectfully note the general rule that what an applicant states in his or her specification is to be accepted by the PTO in the absence of evidence or good reasoning to the contrary. Cases which support Appellants' position include *In re Costello*, 178, USPQ 290, 292; *Ex parte Johnson*, 40 USPQ 576; *In re Andrews*, 160 USPQ 360, 366; *Ex parte Leonard*, 187 USPQ 122, 123-124. The present Appellants submit and believe that there is no evidence or good reasoning which is contrary to what is stated in Appellants' specification as regards the state of the prior art, the problems which existed in the prior art, and the advantages achieved by the present invention.

The paragraph on page 9 of Appellants' specification, first two lines, states as follows:

Lycopene in the coloring material of the present invention is in the concentration range from 500-3,000 ppm, which is at least ten-fold the concentration of lycopene in whole native tomatoes, which is in the range of 50 to 100 ppm.

Claim 8, the first method claim recites that the process "is carried out under conditions providing said chromoplast particles containing crystalline lycopene in said solid material thereby obtaining a color concentrate comprising said color-imparting agent," and further recites that the resultant "coloring material comprises from 500 to 3,000 ppm of lycopene...." Claim 8 does not require any particular concentration of lycopene in the resultant color concentrate, but that it only be somewhere in the range of 500-3,000 ppm of lycopene.

Again, this is fully consistent with the description of the invention in Appellants' specification at the top of page 9.

The rejection is unjustified and should be reversed. Such is respectfully requested.

II- Applicants' Claims are Fully Enabled

The examiner says that Appellants' specification does not enable the person skilled in the art to extract the

chromoplasts from the fruit without causing substantial mechanical breakage or destruction of the chromoplasts. This is incorrect.

Appellants' specification states as follows at page 7, top paragraph, with particular emphasis on lines 8-10, as follows:

Upon breakage and fractionation of tomato fruit into soluble and insoluble fractions, the chromoplasts are found in the insoluble fraction in concentrated form. The intense red color of lycopene is absolutely dependent on its intact crystalline structure;... That is, the crystalline structure of lycopene is more readily preserved therein, and is not destroyed or otherwise changed as occurs [in the prior art] with rigorous extraction of the chromoplasts. (bracketed material added)

The present invention is therefore clearly indicated as being carried out without "rigorous extraction of the chromoplasts", thus preventing substantial destruction of the chromoplasts.

As pointed out in Appellants' specification, centrifugation is known in the art to be a gentle separation process, and this is confirmed in paragraph 2 of Dr. Hartal's declaration. Such separation is exactly what is disclosed in Appellants' specification (see page 11, lines 8 and 19, page 13, lines 5 and 13). This separation process is also shown in the examples, attention being invited to the fifth line of Example 1, the second line of Example 2 and the fourth line of

Example 3. That simple centrifugation works is shown by the results which the Appellants obtained.

Certainly those skilled in the present art would have no trouble practicing Appellants' invention based on their common knowledge coupled with Appellants' disclosure as noted above that the separation should be gentle in order to minimize breakage of the chromoplasts. Indeed, Appellants believe that there would be no experimentation necessary at all. However, if any experimentation were necessary, it would at most be routine experimentation which is well accepted to be permissible under 35 U.S.C. 112. Thus, Appellants respectfully submit that little or no experimentation would be necessary, taking into account the fact that centrifugation is known in the art to be gentle, coupled with Appellants' examples and the results obtained.

The product claims as represented by claim 1 do not require any particular process. Once the person skilled in the art reads Appellants' specification and learns that an objective is to minimize fracturing of the chromoplasts, such person skilled in the art will now how to proceed.

The process claims as represented by claim 8 specifically call for separating by centrifugation. The person skilled in the art, upon reading appellants'

specification, will know to carry out centrifugation in such a way as to minimize fracturing of the chromoplasts.

The examiner, in the final rejection in the top paragraph on page 3, refers to page 9 of paper 9 (presumably Appellants' Reply of March 30, 2001) as allegedly stating that Appellants' centrifugation is "not essentially different [than] those conventionally carried out in the tomato processing industry" (bracketed material of examiner). While Appellants are unable to find such quotation at page 9 or anywhere else, Appellants do agree that centrifugation is known in the prior art. But this is not the end of the matter, because centrifugation in the prior art is invariably carried out without regard to whether or not the chromoplasts are fractured; and, more importantly, tomato-based products in particular are always heated substantially in the prior art. Such heating, particularly when employed with mechanical separation, destroys the chromoplasts (see paragraph 4 of Dr. Hartal's declaration).

The rejection is unjustified and unsupported, and should be reversed. Such is respectfully requested.

III- Appellants' Claims Meet the Requirements of the Second Paragraph of §112

Appellants are puzzled by the rejection of claims 1-14, 23-28 and 41-44 under the second paragraph of §112, as

only claim 5 is criticized as being indefinite in the Final Action (middle paragraph on page 4). It therefore follows that the rejection does not apply at all, i.e. it totally without basis, with respect to claims 1-4, 6-14, 23-28 and 41-44.

As regards claim 5, appellants' specification states (second sentence of top paragraph on page 9) as follows:

The higher limit of the concentration range of the coloring material of the present invention may be achieved using as a starting material a tomato variety which is especially rich in lycopene.

These tomatoes are known. What an applicant states in his specification is to be accepted by the examiner in the absence of evidence or good reasoning to the contrary, noting the case law cited in footnote 4, *supra*. The examiner has no evidence or good reasoning to the contrary, but simply says that what is recited in claim 5, namely "a high lycopene-content tomato variety" cannot be ascertained by those skilled in the art, and therefore the claim is indefinite. But as the examiner has no evidence or good reasoning, he has not meet his burden.

If any evidence were needed, it can be found in Dr. Hartal's Declaration, noting paragraph 7 at the top of page 4 which states as follows:

7. High lycopene content tomatoes are well known. While conventional ripe tomatoes contain 60-100 ppm of lycopene, the high

lycopene content tomatoes contain a lycopene content of about 160 ppm or more.

To summarize, the rejection is based in speculation whereas Dr. Hartal's Declaration is based on his knowledge of the facts. The examiner has provided no evidence or good reasoning to the contrary.

The examiner's position seems to be that the mere inclusion of the word "high", regardless of the circumstances, renders a U.S. claim "indefinite" under the second paragraph of §112. But that is not correct. The Supreme Court of the United States, in a ruling which has not been overturned by any later Supreme Court decision or by statute, in the famous *Eibel* case, *Eibel Process v. Minnesota & Ontario Paper*, 261 US 45, approved the term "high".

Also please see *Charvat v. Commissioner*, 182 USPQ 77, 585, where "high concentration" was found to be acceptable. In *Ex parte Romentschuk*, 188 USPQ 542, the terminology "small amount" was found to be acceptable. The term "high" in Appellants' claim 5 is not indefinite, because it would be well understood by those skilled in the art upon reading Appellants' specification, again noting paragraph 7 of Dr. Hartal's Declaration.

As of June 3, 2003, the word "high" had appeared in the claims of 235,418 U.S. patents issued since 1976, showing that the term "high" is ubiquitous in U.S. patent claims.

Attention is respectfully invited to *Ex parte Brian et al*, 118 USPQ 242, 245 (1958) where the Board stated in part as follows:

..., Appellants have referred to numerous patents dealing with the subject matter involved in the present case, which have been allowed on the basis of claims [using particular] characteristics.... Since the claims under consideration are similar to those in the patents, we do not feel disposed to reject them and thus upset such a long established practice in the particular art under consideration. Accordingly, we will not sustain the rejection....

Accordingly, claim 5 is not indefinite simply because it includes the term "high".

Appellants respectfully request reversal of the rejection based on the second paragraph of 35 U.S.C. 112.

IV- Graves Does Not Anticipate Any of Claims 1-14, 23-25, 28 or 45

Graves, which is acknowledged prior art and is discussed in the top paragraph on page 4 of Appellants' specification, is antithetical to the present invention. In this regard, Graves states as follows at column 3, lines 16-19:

Disruption of the cell structure of the carotenoid source during separation generally inherently results in transfer of the carotenoid(s) in the carotenoid source from the pulp fraction to the liquid fraction.

This disruption of the cell structure, i.e. destruction of the chromoplast membrane, is exactly what Appellants wish to and have substantially avoided, and what gives Appellants' product improved resistance to oxidation and resistance to loss of the deep red color. This is clear from the language of claim 1, which states in part as follows:

A coloring material in the red color range comprising,
chromoplasts particles encapsulating crystalline lycopene..., ...
wherein the coloring material comprises... **said chromoplast particles encapsulating crystalline lycopene**, and...

If the cell structure of the carotenoid source is disrupted as required by Graves, then clearly Graves does not provide chromoplast particles encapsulating crystalline lycopene, a key feature of the present invention, and a feature called for in all of Appellants' claims.

Graves clearly does not disclose (and therefore does not anticipate) a coloring material of lycopene-containing chromoplast particles, let alone such a composition comprising 500-3,000 ppm thereof wherein the material has a soluble solids concentration below 5° Bx.

As regards Appellants' claim 4, Graves also does not show a coloring material which has been water washed.

As regards Appellants' claim 5, Graves does not show a coloring material which has been derived from a high lycopene-content tomato variety.

As regards claim 8, Graves does not show a process as recited, which

is carried out under conditions providing said chromoplast particles containing crystalline lycopene....

In addition, step (d) of claim 8 recites the following operation:

separating by centrifugation a fruit serum from a solid material thus obtained and **retaining said chromoplast particles with said solid material,....**

This is also is inconsistent with Graves which discloses **working with the liquid fraction**, contrary to the present invention, i.e. the Graves second step is

(ii) treating the carotenoid-containing **liquid** fraction with a carotenoid precipitation agent including calcium chloride, calcium hydroxide, calcium lactate or calcium gluconate, so as to fractionate the **liquid** fraction into a carotenoid-enriched solid precipitate portion and a carotenoid-depleted liquid portion,....
(emphasis added)

Then, as indicated above, Graves further teaches away from the present invention by emphasizing the necessity of disruption of the cell structure of the carotenoid source (column 3, lines 16-19). See paragraph (a) on page 4 of Dr. Hartal's declaration.

If there were any doubt, that doubt should be laid to rest by Dr. Hartal's statement in paragraph (a) on page 4 of his Declaration, as follows:

(a) As regards the Graves document, it is clear that Graves is working with the liquid fraction. Graves specifically refers to "cell disruption" and this certainly means of destruction of the chromoplast membrane.

The examiner has only unsupported speculation to the contrary, which is not even reasonable.

Claim 10 adds the operation of water washing the color concentrate, which is not disclosed by Graves.

Claim 11 adds the operation of processing the color concentrate to avoid microbial spoilage, and there is not such disclosure in Graves. Claim 12 adds to claim 10 the option of a variety of preservation techniques, none of which are disclosed by Graves.

Claim 13 is effectively a method of use claim. It calls for adding the coloring agent of claim 1 to another tomato product to provide a tomato product of constant color. There is not the remotest suggestion in Graves of any such method.

Claim 14 defines a tomato product which has been colored with the coloring material of claim 1. There is no such disclosure of any such product in Graves.

Claim 24 is an independent claim along the lines of dependent claim 13, but which requires the use of tomatoes comprising chromoplasts containing lycopene in the amount of at least 120 ppm. There is no such disclosure in Graves. Claim 24 further defines over Graves in the same way as does claim 8, and further in the same way as claim 12.

Claim 25 defines over Graves in the same as claim 24, and further requires an additional washing step of the color concentrate if the food product to which the color concentrate is added is not a tomato product, also not disclosed by Graves.

Claim 28 depends from claim 24 and thus defines over Graves for the same reason as claim 24, and further requires the additional step of subjecting the color concentrate to at least one preservation technique of septic packaging, canning, freezing or dehydrating.

Claim 45 is a Jepson form claim similar to claim 13, but additionally specifically reciting the steps of claim 8 as well as the step of claim 13. Thus, claim 45 defines over Graves for the same reasons as pointed out above with respect to claims 1, 8 and 13.

The present invention is clearly fundamentally different from Graves: in the present invention, after gentle separation of the solids from the liquid by centrifugation,

Appellants obtain the chromoplast encapsulated lycopene from the solid fraction, and avoid disruption of the chromoplast as much as is reasonably possible. Graves is totally antithetical to the present invention.

Graves does not anticipate any of Appellants' claims, and the rejection under §102 based on Graves should be reversed. Such is respectfully requested.

V- Claims 14 and 41-43 are Novel Over Tonnuci

Tonnuci involves a study of commercially processed tomato-based food products (last paragraph on first page). Table 2 on page 583 shows the lycopene content of various tomato based products including tomato soup, tomato juice and vegetable juice; and Table 3 on the following page shows the lycopene content of catsup, spaghetti sauce, tomato paste, tomato puree and tomato sauce. Tonnuci thus relates to commercial tomato-based products such as soups, canned tomatoes, ketchup, spaghetti sauce, tomato paste, tomato puree, tomato juice and tomato sauce.

The rejection from an earlier Office Action (incorporated by reference into the Final rejection) focuses

on Table 3 which shows that tomato paste⁵ has a lycopene content (according to the rejection) of around 550 ppm. But tomato paste has a Brix value of approximately 30° Bx (see paragraph 6 of Dr. Hartal's declaration), far more than what is permitted according to the present invention.

All of the Tonnuci products are commercial products taken so-called "off the shelf". All of these commercial products are subjected to substantial heat during their preparation, causing considerable deterioration of the chromoplasts.

Claim 14 calls for a tomato product colored with the color concentrate of claim 1. This requires, first, a tomato product, of which Tonnuci shows many. However, claim 14 then requires that such tomato product be modified by being colored with the material according to claim 1. As Tonnuci does not disclose the material of claim 1 or anything remotely similar, Tonnuci does not anticipate claim 14. The same applies to claims 41 and 42.

Claim 43 requires that product of claim 41 be subjected to water washing. There is no such disclosure in

⁵The earlier final Action, incorporated by reference into the last rejection, also states on page 14, paragraph 56 that it is "well known that tomato juices will have Brix values of around 5, even less than 5." Regardless, no tomato juice would correspond to Appellants' claims because the chromoplast particles will have largely been destroyed by heating to make the canned tomato juice safe, and tomato juice will not contain 500 to 3,000 ppm of chromoplast particles as claimed, i.e. tomato juice contains no more than about 100 ppm, again noting paragraph 5 of Dr. Hartal's declaration. Please also see the documentary evidence filed August 1, 2003, in support of Dr. Hartal's declaration.

Tonnuci, and therefore claim 43 defines over Tonnuci for this additional reason.

Therefore, the commercial products as disclosed by Tonnuci cannot meet any of Appellants' claims wherein the chromoplasts encapsulate the lycopene, it being understood that the chromoplasts in the present invention are largely or even substantially intact; and cannot meet any of claims 14 and 41-43 which require the aforementioned concentrate to be added to a food product, no such admixture being disclosed by Tonnuci.

The rejection under §102 based on Tonnuci should be reversed, and such is respectfully requested.

VI- Claims 1-3 and 5-7 are Novel Over Brumlick

Brumlick, similar to most of the other citations, is interested in a commercial way of making food products including tomato-based or tomato flavored foods or concentrates. In every case as shown in Fig. 1 and described at column 2, lines 57-61, the vegetable juice, separated from the vegetable solids "is passed through one or more filters in a filtering step 15 followed by **evaporating or distilling operations 16** in which a substantial amount of the liquid or water is removed to provide a thick, viscous residue 17." (emphasis added).

Here again, as in Graves discussed above, Brumlick is working with the liquid fraction (absolutely contrary to the present invention) rather than the solid fraction. Then, to make Brumlick even more distinct from the present invention, the liquid is subjected to high heat which would inevitably destroy any chromoplasts present in that fraction. Indeed, the resultant thick, viscous residue 17, obtained after distilling off the water, is then subjected to even more heat in a radiation step 21 "which is sufficient to toast the material...." (Column 3, line 4). Please again see the last sentence of paragraph 1 of Dr. Hartal's attached declaration which makes clear that such heating must be avoided to obtain Appellants' results. Item 4, two documents attached to the Submission of Documentary Evidence in Support of Dr. Hartal's declaration, also confirm the damaging effects of heat.

To briefly summarize, Brumlick involves distilling steps and toasting steps (e.g. Fig. 1; column 2, lines 57-61; column 3, line 4; and the examples), i.e. high heat, destructive of the chromoplast membrane.

As regards claim 5, Brumlick does not disclose the use of high lycopene-content tomatoes.

Clearly, Brumlick does not anticipate any of Appellants' claims 1-3 or 5-7, and the rejection should be reversed. Such is respectfully requested.

VII- Claims 1-3, 5, 6, 13 and 14 Define Novel Subject Matter
Over Szabo

Szabo relates to the manufacture of tomato puree. As indicated above, in the manufacture of such commercial products, the tomato material is inevitably heated to a relatively high temperature which inevitably results in the destruction of the chromoplasts.

Exactly what Szabo does is somewhat unclear⁶. However, it appears that after breaking, Szabo obtains a tomato juice (see Fig. 1). Such juice, containing tomato colloids having negative electric characteristics (column 1, lines 45 et seq.) is then subjected to coagulation, preferably using calcium ions.

Next, a "considerable parts of the serum can be decanted and evaporated." (column 2, lines 14-15). Presumably evaporation involves **substantial heat**. (Bradley says that Szabo "degrades the cellular structure of the tomato macerate.") Evaporation is also mentioned at column 2, lines 19-30, and it is unclear whether this is the same evaporation or a further evaporation. What is obtained eventually is a concentrated serum which smells of tomato (column 2, lines 37-38), clearly suggesting that the chromoplasts have been destroyed, which is inevitable in any event due to the

⁶ The initial burden is on the examiner. The rejection is based on speculation as to what Szabo did. It is simply not disclosed.

substantial heating applied. Also see column 3, lines 5-10 in this regard.

The resultant product of Szabo is a tomato puree which "has an attractive appearance, smells like tomato [and can be used to make "dishes"] which have taste and character similar to those made with the traditional tomato purees." In the present invention, the tomato smell and taste are largely eliminated (because the chromoplasts are maintained as claimed), and this proves that Szabo does not inherently produce Appellants' product. Neither the process nor the product of Szabo correspond to the claimed subject matter.

Claim 5 adds to claims 3 and 1 that the tomato is a high lycopene-content tomato variety, and there is no such disclosure in Szabo.

Szabo does not anticipate any Appellants' claims. The rejection based on Szabo should be reversed, and such is respectfully requested.

VIII- Claims 1-5 and 14 are Novel Over Bradley

As with most of the other references relied upon, Bradley also is concerned with the manufacture of a tomato based food product such as juice, soup, sauces, paste (column 5, lines 12-15). Bradley is particularly interested in a particular part of the overall process involving separating a tomato macerate to a reduced insoluble solids pulp fraction

and an insoluble solids-enhanced pulp fraction. At the very beginning, after chopping the fresh tomatoes, they "are heated to inactivate enzymes" (column 3, lines 6 and 7), and this will destroy chromoplasts. If the tomatoes are macerated using the hot-break method, they are heated to 60-100°C, preferably at least 85°C (column 3, lines 25-30).

Bradley appears to favor the hot-break⁷ procedure, and in this regard suggests higher temperatures for better consistencies, noting column 5, lines 7 and 8:

Generally higher break temperatures yield higher consistencies for both fractions.

In the illustrated embodiment, hot-breaking is disclosed, noting the hot-break tanks 110 and 120 (see column 8, lines 3 etc.). In the sole example (column 9), a hot-break tomato macerate is used.

As pointed out above, Bradley also discusses the aforementioned Szabo patent and basically confirms Appellants' position noting column 5, lines 44-50 as follows:

Secondly, the mechanical separation procedure of the prior art [Szabo (see col.5, ll. 19 and 20 of Bradley)], i.e. high speed centrifugal separation, unavoidably **degrades** the cellular structure of the tomato macerate,... This **degradation** unavoidably impairs the ultimate consistency obtained in subsequently obtained tomato products. (emphasis added)

⁷ But even the cold-break procedure normally involves substantial heating, noting the Lang reference discussed below.

While the separation practiced by Bradley is apparently less vigorous than that practiced by Szabo, Bradley explicitly does not avoid the use of heat. The "rough handling and heat" carried out and taught by Bradley "inevitably results in the destruction of chromoplasts and in oxidization of lycopene", noting paragraph (d) of the Hartal Declaration, which states as follows:

(d) The Bradley document subjects the tomato parts to rough handling and heat, and this inevitably results in the destruction of the chromoplasts and in oxidation of lycopene. This document states that the chopped tomatoes "are heated to inactivate enzymes", and this will inevitably destroy chromoplasts.

In the end, Bradley does not and cannot obtain what is claimed in claim 1, namely

A coloring material in the red color range,
comprising
chromoplast particles encapsulating crystalline
lycopene as the color-imparting agent,
said chromoplast particles being particles separated
from a fruit which contained them,
wherein the coloring material comprises from 500 to
3000 ppm of said chromoplast particles encapsulating
crystalline lycopene, and
wherein the coloring material has a soluble solids
concentration below 5° Bx.

As regards claim 4, Bradley does not disclose any coloring material which has been water-washed.

With regard to claim 5, Bradley does not disclose starting with a high lycopene-content tomato variety.

Bradley does not anticipate any of Appellants' claims. The rejection should be reversed and such is respectfully requested.

IX- None of Appellants' Claims 1-5, 7, 13 or 14 is Anticipated
By Lang

Lang suffers from many of the deficiencies of the references already discussed above in the manufacture of a tomato based product for storage and consumption. Heating is unquestionably an aspect of the Lang process; and, interestingly, Lang defines even the "cold break" method as involving temperatures of 70-75°C (column 2, lines 3-9) with tomatoes processed according to the "hot break" method being heated to 95-100°C.

In Lang, the tomato slices are heated to a temperature of at least 65°C (abstract line 5; column 2, lines 28-31), and more preferably at least 75°C (column 2, lines 64). Apparently, **the temperature must be sufficiently high to denature the polygalactonase in the tomatoes** (column 2, lines 3 and 4; lines 67 and 68). In the illustrated embodiment, the tomato serum is heated to approximately 95°C (column 4, lines 24-25). As pointed out above, the processing including such heating inevitably ruptures the chromoplast walls. See

paragraph (f) of the Hartal Declaration, which states as follows:

(f) The Lang citation mentions treatment of tomato by either a "cold break" method or "hot break" method. The cold break method involves temperatures of 65-70°C and the hot break method involves temperatures of at least 95°C. The temperature must be sufficiently high, according to the Lang citation, to deactivate the pectolytic enzymes in the tomatoes. Following what Lang says to do will result in destruction of the chromoplasts.

Dr. Hartal, an expert in this art, is entitled to provide statements of fact based on his knowledge and experience.

As with the other prior art documents discussed above, Lang does not and cannot obtain the claimed subject matter including chromoplast particles encapsulating crystalline lycopene, wherein the coloring material comprises from 500-3,000 ppm of the chromoplast particles, and wherein the coloring material has a soluble solids concentration below 5 degrees Brix, as claimed.

There is no "reasonable certainty" or inevitably that Lang inherently produces the claimed subject matter⁸, and

⁸ The basis of most of the prior art rejections relied upon by the examiner is somewhat unclear to Appellants due to the examiner in each Office Action referring to the "reasons set forth in the last Office Action". Appellants are thus unsure whether or not the examiner is taking the position that Lang (and /or other citations relied upon) inherently provide the subject matter of claim 1. But there is no inherency under the law, unless the inherency is "certain", noting *Ex parte Cyba*, 155 USPQ 756, 757 (1967), or is "inevitable", noting *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981), or is reasonably certain, noting *In re Brink*, 164 USPQ 247, 249.

indeed it is clear that Lang does not and cannot do so.

Neither Lang nor any of the other prior art relied upon inherently provides appellants' claimed subject matter.

Claim 4 adds to claim 1 that the coloring material has been water-washed, and this feature is not disclosed by Lang

Claim 5 adds to claims 3 and 1 that the tomato is a high lycopene-content tomato variety, and this is another feature not disclosed by Lang.

Claim 13 calls for a method by which a tomato product is provided with a consistent color, "comprising adding to said tomato product a coloring effective amount of a coloring material as defined in claim 1." Lang shows no such method.

Claim 14 calls for a tomato product which has been colored with the coloring agent of claim 1. Lang discloses no such product.

Lang does not anticipate any of Appellants' claims. The rejection based on Lang should be reversed, and such is respectfully requested.

X- Claims 26 and 27 Define Non-Obvious Subject matter over Graves In View of Horn

Claim 26 depends from and incorporates the subject matter of claim 24. Claim 27 depends from claim 26 and

incorporates the subject matter of claim 26 (including claim 24).

Graves has been discussed above where it has been pointed out how Appellants' claims define over Graves. Horn has not been cited to make up for what Applicants have pointed out that Graves does not have. Therefore, even if the combination were obvious (not conceded by Appellants), the resultant combination would not correspond to what is claimed.

The statement of this rejection appears to go back to the Office Action mailed March 25, 1998, in application 08/507,632, at pages 6 and 7. As understood, Horn is relied upon to "teach the prior art use of a colloid mill to reduce the size of carotenoids to increase their solubility". The rejection states that it "would have been obvious to those of ordinary skill in the art to use the colloid mill of the prior art, as taught by Horn et al, in the process of Graves et al for its intended and well taught use." However, this would in no way lead to the present invention, even if such a combination were obvious. The addition of Horn to Graves does not do away with the teaching of Graves to disrupt the cell structure of the carotenoid.

Nowhere in the prior art is it taught that one should try to **not** disrupt the chromoplasts membrane, which is a key aspect of appellants' invention. Accordingly, even if

the combination were obvious, it would not lead to the present invention.

Claims 26 and 27 would not have been obvious to the person of ordinary skill in the art at the time the present invention was made. Appellants respectfully request reversal of this rejection.

XI- Claims 1-5, 7, 13 and 14 Would Not Have Been Obvious From
A Consideration Of Lang In View Of Brumlick

The statement of this rejection appears to go back to pages 8 and 9 of the Office Action of August 20, 1996, in application 08/507,632. Both Lang and Brumlick have been discussed above; appellants believe they are substantially cumulative. Even if it were obvious to combine them as proposed, the results of such a combination would not correspond to appellants' claimed subject matter.

The ways in which the present invention as called for in claim 1 defines over Lang have been discussed above. Brumlick does not make up for these differences and has not been cited to do so. Therefore, even if the proposed combination were obvious, not admitted by Appellants, the resultant combination would not correspond to the subject matter of claim 1 or any of the claims dependent thereon.

Claim 4 adds to claim 1 the feature of the coloring material having been water-washed, and this is not disclosed

by either Lang or Brumlick, and therefore no possible combination of the two can meet this additional feature.

Claim 5 adds to claim 3, including claim 1, that the tomato starting material is "a high lycopene-content tomato variety." This added feature is not shown by either Lang or Brumlick, and therefore cannot be achieved by any combination of these citations, even if obvious.

None of claims 1-5, 7, 13 or 14 would have been obvious to a person of ordinary skill in the art at the time Appellants' invention was made from a consideration of Lang in view of Brumlick. Accordingly, Appellants respectfully request reversal of this rejection.

XII- Claims 1-14, 24-28 And 45 Define Non-Obvious Subject Matter Over Tonnuci In View Of Dale

The statement of this rejection appears to go back to pages 6 and 7 of the Office Action of April 7, 1997, in application 08/507,632. Both Tonnuci and Dale are directed to the same general subject matter, i.e. tomato concentrates of one type or another. They both lack key features of the present invention as pointed out above, and any possible combination of the two, even if obvious, could not possibly result in appellants' claimed subject matter.

Tonnuci has been discussed above. Dale discloses heating, which inevitably destroys the chromoplasts.

As is clear from the abstract of Dale, the Dale "process alternatives" all involve substantial heating. On the first page, second column under the heading "MATERIALS & METHODS", it is indicated that the chopped tomatoes were heated to 90 C. Such a "hot break" is called for in all five systems of Dale as shown on the following page, and this is followed by more heat, i.e. a triple effect evaporation. All this use of heat is contrary to the present invention, as such heat "will inherently and inevitably result in a deterioration of the chromoplasts" noting paragraph (e) of the attached Hartal declaration.

In the first full paragraph on page 8 of the most recent Final Action, the examiner says that the claims do not exclude heating. However, the claims recite a resultant product which cannot be obtained by the process of Dale.

As noted above, both Tonnuci and Dale relate to commercial tomato based products which have been subjected to substantial heat during their manufacture. No possible combination of these documents, even if obvious, could result in Appellants' color concentrate of claims 1-5 or 7, or in Appellants' process for making such a coloring material as called for in Appellants' claims 8-12, or in Appellants' method of claim 13 whereby "a coloring effective amount of a coloring material as defined in claim 1" is added to a tomato

product to provide that tomato product with a constant color, or the tomato product of claim 14 which is a tomato product colored with a material according to claim 1, or the process for coloring food products as called for in claims 24-28, or the method of claim 45.

The various subsidiary claims have been individually discussed in conjunction with other rejections. To avoid additional prolixity, appellants respectfully repeat by reference the commentary made above with regard to the various subsidiary claims, and respectfully note that features set forth in the dependent portions of subsidiary claims 4, 5, 10 and 25-27 would not be reached by any proposed combination of Tonnuci in view of Dale.

Appellants' claims 1-14, 24-28 and 45 define non-obvious subject matter over Tonnuci in view of Dale. Appellants respectfully request reversal of the rejection.

XIII- Appellants Rebuttal To The Examiner's "Response To Arguments"

Except for the introduction which appears at the bottom of page 6, the examiner's "Response to Arguments" appear at pages 7 and 8 of the final Action of August 1, 2003, Paper no. 28.

In the top paragraph on page 7, the Examiner tries to explain why he believes Tonnuci anticipate claims 14 and

41-43. Unfortunately, this explanation makes no sense to Appellants.

Tonnuci provides tables of different commercial products based on tomatoes. Except for tomato juice, all such products have a soluble solids concentration well above 5° Brix (Bx). Therefore, none of these products anticipate any of Appellant's claims. While tomato juice may indeed have a soluble solids concentrate below 5° Brix, it does not contain chromoplast particles encapsulating crystalline lycopene in an amount falling somewhere in the range of 500-3,000 ppm. Please see paragraphs 5 and 6 of Dr. Hartal's Declaration which confirm these facts, as well as the documentary evidence filed August 1, 2003.

Next, the examiner states that Graves anticipates, even though Graves works with the liquid fraction, because the instant claims are not restricted to non-liquid fractions. But, as pointed out above, claim 8 explicitly recites "retaining said chromoplast particles **with said solid material**" clearly contrary to Grave.

As regards Appellants' product claims including claims 1-7, 14 and 23, they all call for chromoplast particles encapsulating crystalline lycopene, subject matter which is not possible according to Graves which, as noted above, emphasizes the necessity of disruption of the cell structure.

The Examiner brushes aside Dr. Hartal's Declaration as being "not based on any evidence and therefore is not found persuasive." But Dr. Hartal's Declaration is evidence. The Examiner seems to erroneously believe that only Declarations which provide comparative results are entitled to any weight, but this is not correct, noting for example *In re Alton*, 37 USPQ2d 1578, 1583-84 (Fed Cir 1996). Dr. Hartal is an expert in this art, and even his opinions are entitled to substantial weight. The statements which the Examiner brushes aside are more than opinions, i.e. they are statements of fact based on Dr. Hartal's experience.

The Examiner says that Appellants disrupt cells, and "it is not seen that Graves does anything differently." With respect, appellants do not see how such a statement can be reasonably made in view of the fact that appellants do everything they can to not disrupt cells, whereas Graves emphasizes necessity of the disruption of cells. Respectfully, the Examiner's position is akin to saying that night and day are equivalent because the full moon reflects sunlight. The Examiner's position is simply unreasonably.

Next, the Examiner refers to column 4, lines 51-56, of Graves and quotes therefrom "separation of carotenoid-enriched solid precipitate portion from the carotenoid-depleted liquid portion may be achieved by any conventional

method, including centrifugation..." But this quotation is taken out of context. The immediately preceding paragraphs relate to the treatment of the **liquid fraction**, especially of carrot juice. Thus, Graves is discussing further treatment of the **liquid fraction** of carrot juice. Graves states as follows commencing at column 4, line 37:

It is believed that optimal fractionation may also be obtained by treating the **liquid fraction** with one of the listed carotenoid precipitation agents....

Referring to FIG. 4 and Table Four, the pH of the liquid fraction can affect the rate of separation and overall separation efficiency..... Carrot juice having pH adjusted with NaOH as necessary... appears to provide the most complete separation (clearer liquid fraction).... (emphasis added)

So what Graves is disclosing is a further treatment of the liquid fraction, not the solid fraction as in the present invention.

As regards Brumlick, the Examiner states that "the solid material removed in the Brumlick process will contain the lycopene." But Brumlick does not disclose what is done with the solid fraction. Appellants submit that a rejection cannot be based on what Brumlick does not disclose.

With respect to Szabo, the Examiner states that only the serum is taught to have the flavor and aroma of tomatoes. However, Szabo discloses that the "tomato concentrate,

produced according to our method has generally a red colour, ... an attractive appearance, smells like tomato." (Column 3, second paragraph) This is contrary to the present invention.

As regards the combination of Bradley and Lang, it has already been pointed out above that even the cold-break method involves substantial heating according to the prior art.

The Examiner says that the obviousness rejections "meet all of the limitations of the claims and therefore a *prima facie* case of obviousness exists." Appellants have pointed out above that this is not correct.

CONCLUSION

The initial burden is on the Examiner, and the Examiner has not met his burden.

The present invention constitutes an improvement because the lycopene product produced, the subject matter of claim 1, is largely protected from oxidation by the chromoplast shells or capsules, only a small fraction of which are broken (page 7, lines 10-12). Because of the retention of the chromoplast capsule or shell, with the lycopene crystals therewithin, color intensity is maintained due to decreased oxidation.

The present composition is novel and unobvious in that it has both, i.e. in combination, a very low Brix with a very high lycopene content. Commercial tomato based products, with the exception of tomato juice, have a very high Brix; tomato juice, while having a relatively low Brix (about 4.8 - 5.2), also has a much lower lycopene content, i.e. about 60 ppm, and no higher than 100 ppm, compared to the composition of the present invention (see paragraph 5 of Dr. Hartal's declaration).

In the manufacture of tomato based products, the tomato is usually subjected to two unit operations which cause extensive damage to the chromoplasts, these two operations being (1) the application of damaging heat, and (2) the application of intense mechanical activity (see paragraph 4 of Dr. Hartal's declaration). Maintaining a high percentage of intact chromoplasts according to the present invention is essential and is accomplished by avoiding or minimizing these unit operations (see paragraph 1 of Dr. Hartal's declaration). Thus, in accordance with the present invention, the solids are separated from the liquid simply by (gentle) centrifugation (see paragraph 2 of the Hartal declaration).

None of the references even hint at the present invention. Appellants have shown that heat is invariably used in the manufacture of tomato based food products, and that

heat disrupts the chromoplast shell exposing the crystalline lycopene to easy degradation. This is confirmed as factual in Dr. Hartal's declaration. The present invention has solved problems which existed in the prior art, thereby solving a long felt need, and defines novel and unobvious subject matter warranting allowance.

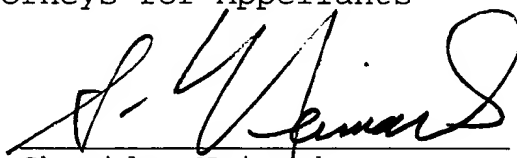
Appellants' claims meet the requirements of §112, define novel and unobvious subject matter under Sections 102 and 103, and should be allowed.

Appellants respectfully repeat that the Examiner has not met his burden. The rejections should therefore be reversed, and such is respectfully prayed.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Appellants

By



Sheridan Neimark
Registration No. 20,520

SN:jaa
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\M\MAKH\Hartel1B\Pto\Brief 29De03.doc

APPENDIX

1. A coloring material in the red color range comprising,
chromoplast particles encapsulating crystalline lycopene as the color-imparting agent,
said chromoplast particles being particles separated from a fruit which contained them,
wherein the coloring material comprises from 500 to 3000 ppm of said chromoplast particles encapsulating crystalline lycopene, and
wherein the coloring material has a soluble solids concentration below 5° Bx.
2. A coloring material according to claim 1, comprising as the color-imparting agent, chromoplast particles comprising crystalline lycopene, and further comprising color-neutral substances wherein the coloring material comprises from 500 to 3000 ppm of lycopene.
3. A coloring material according to claim 1, wherein the chromoplasts are derived from tomatoes.
4. A coloring material according to claim 1, which has been water-washed.

5. A coloring material according to claim 3,
wherein the tomato is a high lycopene-content tomato variety.

6. A coloring material according to claim 1, in a
dehydrated form.

7. A coloring material according to claim 1, in
frozen form.

8. A process for preparing a coloring material
comprising as a color-imparting agent chromoplast particles
containing crystalline lycopene, comprising:

a) selecting and pre-treating a lycopene-containing
fruit by cleaning it;

b) breaking the fruit;

c) screening out solid components above a
predetermined dimension; and

d) separating by centrifugation a fruit serum from a
solid material thus obtained and retaining said chromoplast
particles with said solid material,

wherein said process is carried out under conditions
providing said chromoplast particles containing crystalline
lycopene in said solid material thereby obtaining a color
concentrate comprising said color-imparting agent,

wherein the coloring material comprises from 500 to 3000 ppm of lycopene and wherein the coloring material has a soluble solids concentration below 5° Bx.

9. A process according to claim 8, wherein the fruit is tomato.

10. A process according to claim 8, further comprising water-washing the color concentrate.

11. A process according to claim 8, further comprising processing the color concentrate to avoid microbial spoilage.

12. A process according to claim 10, comprising at least one preservation technique selected from the group consisting of aseptic packaging, freezing, canning and dehydrating, optionally with the addition of a food preservative.

13. A method for producing a tomato product of constant color, comprising adding to the said tomato product a coloring effective amount of a coloring material as defined in claim 1.

14. A tomato product colored with a material according to claim 1.

23. A coloring material according to claim 1, wherein the coloring material comprises at least 1000 ppm of lycopene.

24. A process for coloring a food product which comprises:

a) cleaning and breaking tomatoes which comprise chromoplasts containing lycopene in the amount of at least 120 ppm;

b) screening out solid components therefrom of a predetermined size; and

c) separating a serum from a screened tomato solid material by centrifugation and retaining said chromoplasts with said tomato solid material,

wherein said process is carried out under conditions providing said chromoplast particles containing crystalline lycopene in said tomato solid material,

thereby to obtain a color concentrate comprising said chromoplasts containing crystalline lycopene in a concentration from 500 to 3000 ppm, and

d) introducing said concentrate into said food product.

25. A process according to Claim 24 wherein unless said products are not tomato products, further comprising washing the color concentrate.

26. A process according to claim 24 which comprises subjecting the color concentrate to size reduction.

27. A process according to claim 26, wherein the size reduction is carried out by processing the color concentrate in a colloid mill or microcutter.

28. A process according to claim 24 further comprising processing the color concentrate prior to using it as a coloring material by subjecting it to one or more of the following preservation techniques: aseptic packaging, canning, freezing or dehydrating.

41. In a food product or a health-promoting and health-maintaining consumable product comprising a lycopene additive of lycopene molecules as a food colorant or as a nutraceutical, the improvement wherein

said lycopene molecules are in crystalline form encapsulated in chromoplasts,

said chromoplasts are particles separated from a fruit which contained them,

the lycopene additive comprising from 500 to 3,000 ppm of said chromoplasts encapsulating said lycopene molecules, and

wherein said lycopene additive has a soluble solids concentration below 5° Bx.

42. The food product or health-promoting and health-maintaining consumable product of claim 41, wherein said chromoplasts are derived from tomatoes.

43. The food product or health-promoting and health-maintaining consumable product of claim 41, wherein said chromoplasts have been water-washed to remove flavors.--

45. In a method for coloring a food product or a health-promoting and health-maintaining consumable product, comprising adding a lycopene additive as a red food colorant to said food product or health-promoting and health-maintaining consumable product, the improvement wherein:

said lycopene additive comprises chromoplast particles encapsulating crystalline lycopene,

said chromoplast particles are particles separated from a fruit which contained them,

the lycopene additive comprises from 500 to 3,000 ppm of said chromoplasts particles encapsulating crystalline lycopene, and

the lycopene additive has a soluble solids
concentration below 5° Bx.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:)	Art Unit: 1761
)	
Dov Hartal et al)	Examiner: C.E. Sherrer
)	
Appln. No.: 09/449,093)	Washington, D.C.
)	
Date Filed: November 24, 1999)	December 29, 2003
)	
For: NATURAL COLORING PRODUCTS)	Confirmation No.: 5856
)	
)	ATTY.'S DOCKET: HARTAL=1B

BRIEF ON BEHALF OF APPELLANTS

Customer Window, Mail Stop APPEAL BRIEF-PATENTS
Honorable Commissioner for Patents
Arlington, VA 22202

Sir:

The present Appeal is taken from the Action of the examiner in finally rejecting claims 1-14, 23-38 and 41-45. A clean copy of these claims, double spaced, appears in the Appendix to this Brief.

REAL PARTY IN INTEREST

The real party in interest is Lycored Natural Products Industries, Ltd. which is a subsidiary of Makhteshim-Agan Industries Ltd.

RELATED APPEALS AND INTERFERENCES

Undersigned is aware of no related appeals or interferences.

STATUS OF THE CLAIMS

All the claims are rejected.

STATUS OF AMENDMENTS

All amendments have been entered.

SUMMARY OF INVENTION

The present invention relates to a concentrated lycopene product (specification page 1, second paragraph¹; page 9, second paragraph) in which the lycopene is largely protected from oxidation by the chromoplast shells or capsules which surround the lycopene, a small fraction of which are broken (page 6, last paragraph; page 7, lines 10-12). Because of the retention of the chromoplasts capsule or shell, with the lycopene therewithin, color intensity is maintained due to decreased oxidation of the lycopene, whereby the concentrated lycopene product of the present invention is a highly desirable red coloring material for food and other products (page 1, second paragraph; page 5, second through fourth paragraphs), as well as a neutraceutical (page 6, third and last paragraphs).

A problem which has existed in the prior art with attempts to provide coloring materials in the yellow-red color range from natural sources, which are not suspected of being harmful to health, is the fact that (1) the coloring potency of such materials is usually inferior to that of synthetic colorants, and (2) such natural coloring materials tend to change their color as a result of pH changes or due to oxidation, and "are often readily destroyed by [only] moderate heat." Heating is therefore disadvantageous, and the problem with conventionally extracted lycopene is that its exposure to oxygen, particularly under the effects of even only moderate heat, causes the lycopene to lose its bright red color (page 1, fourth paragraph).

A problem which therefore faced the Appellants was how to prevent color change, especially due to oxidation, and how to provide a high coloring potency by the use of lycopene, bearing in mind that conventional methods of extraction of lycopene from plant sources, particularly tomatoes, tends to destroy the crystalline structure of the lycopene pigment, thus altering its red color to orange-yellow, similar to the color obtainable with beta-carotene (page 2, lines 2-6).

It is of course known to produce tomato products rich in lycopene, e.g. tomato sauce, tomato paste, tomato

¹ Unless otherwise indicated references hereinafter are to Appellants' specification.

juice, etc., as acknowledged in the middle paragraph on page 4 of Appellants' specification:

Many processes are also known in the art for producing tomato pastes and concentrates, products which do indeed contain high concentrations of lycopene. However, these products also contain high concentrations of those tomato components which contribute aroma, viscosity and flavor to the final product. These latter properties are contributed by the soluble solids present in tomato. In the tomato, soluble solids constitute about 5% by weight of the whole fruit. The insoluble solids, which include the lycopene-containing chromoplasts, constitute about 1% of the weight of the fruit, while the remaining 94% is contributed by water. In the production of tomato paste, only water is removed, thus increasing the concentrations of both the soluble and insoluble solids by the same ratio.

Appellants' specification continues in this regard in the bottom paragraph on page 4 as follows:

In the field of food technology, the soluble solids content of foods is frequently reported in degrees Brix, ($^{\circ}\text{Bx}$) which is a measurement of the light refraction of the dissolved solids, expressed as sucrose. While a native whole tomato contains approximately 5°Bx of soluble solids, commercially available tomato pastes contain about 30°Bx . Similarly, while a native whole tomato typically contains approximately 70 ppm lycopene, commercially available tomato pastes contain approximately 350 to 400 ppm lycopene. Hence, while tomato paste is enriched about 6-fold in lycopene concentration, taking into consideration losses incurred upon processing, tomato paste is also enriched

about 6-fold in the concentration of the components which contribute tomato flavor.

This is basically what the prior art discloses. In addition, the processes of making these conventional tomato products causes destruction of the chromoplast membrane.

The present invention solves the problems inherent in the prior art, especially the problem with conventionally extracted lycopene involving its exposure to oxygen under moderate heat which causes it to lose its bright red color. Thus, from the top of page 7 of Appellants' specification:

Naturally occurring chromoplasts present in fruits are small natural double-membrane capsules. Chromoplasts present in lycopene-rich fruit, such as tomato, contain lycopene in crystalline form, and in varying concentrations and crystal sizes. Upon breakage and fractionation of tomato fruit into soluble and insoluble fractions, the chromoplasts are found in the insoluble fraction in concentrated form. The intense red color of lycopene is absolutely dependent on its intact crystalline structure; hence it is likely that keeping the lycopene associated with the chromoplasts, either intact or partially broken, is instrumental in maintaining the red color. That is, the crystalline structure of lycopene is more readily preserved therein, and is not destroyed or otherwise changed, as occurs with rigorous extraction of the chromoplasts.

A key aspect of the present invention therefor is to liberate the chromoplast from the fruit without causing substantial mechanical breakage or destruction of the chromoplast

membrane. This is summarized at the bottom of page 6 of Appellants' specification as follows:

The coloring material of the invention comprises, as the color-imparting agent, intact and partially broken chromoplast particles containing crystalline lycopene, separated from the fruit which contained them, and from the bulk of the flavor-imparting components of the fruit. Said chromoplast particles containing crystalline lycopene also comprise a neutraceutical, natural lycopene being an effective antioxidant, useful for promoting and maintaining human health.

And at the end of the first paragraph on page 7:

Additionally, the chromoplast particles containing crystalline lycopene, separated from the fruit which contained them, have been found to be relatively insensitive to the effects of heat and oxidation, which strongly and adversely affect pure lycopene.

The present invention effectively achieves the objective of providing a highly concentrated lycopene product having simultaneously a soluble solids concentration below 5° Bx and a high concentration (500-3,000 ppm) of crystalline lycopene mostly encapsulated within the chromoplasts and thereby protected from oxidation, thus providing a bright red coloring material which also is a neutraceutical. From the top paragraph on page 9:

Lycopene in the coloring material of the present invention is in the concentration range from 500 to 3000 ppm, which is at least 10-fold the concentration of lycopene found in whole native tomatoes, which is in the range from 50 to 100 ppm. At the same

time, the concentration of soluble solids in the coloring material of the present invention is no greater than 5° Bx, which is approximately the same concentration of soluble solids found in whole native tomatoes. That is, the red color potency of the coloring material of the present invention is approximately 10-fold that of whole native tomatoes, while the flavor value of the coloring material of the present invention is not at all concentrated.

ISSUES

There are many issues due to the many rejections.²

A first issue is whether or not claims 1-14, 23-28, 44 and 45 meet the "description" requirement of the first paragraph of §112.

A second issue is whether claims 1-14, 23-28 and 41-45 meet the enablement requirement of the first paragraph of §112.

A third issue is whether or not claims 1-14, 23-28 and 41-44 meet the requirements of the second paragraph of §112.

A series of issues exist as to whether or not appellants' claims are anticipated by the disclosures of certain citations as outlined below, and thus properly rejectable under §102:

² Appellants' apologize for the length of this Brief which, however, is necessitated by the prolixity of the rejections. Appellants' submit that such a multiplicity of rejections is contrary to at least the spirit, if not the letter, of MPEP 706.02.

whether or not claims 1-14, 23-25, 28 and 45 are properly anticipated by Graves et al USP 5,245,095 (hereinafter "Graves");

whether or not claims 14 and 41-43 are anticipated by Tonnuci et al, Journal of Agriculture and Food Chemistry (hereinafter simply "Tonnuci");

whether or not claims 1-3 and 5-7 are anticipated by Brumlick et al USP 4,181,743 (hereinafter simply "Brumlick");

whether or not claims 1-3, 5, 6, 13 and 14 are anticipated by Szabo et al USP 3,864,504 (hereinafter simply "Szabo");

whether or not claims 1-5 and 14 are anticipated by Bradley USP 4,670,281 (Bradley);

whether or not claims 1-5, 7, 13 and 14 are anticipated by Lang USP 5,229,160 (Lang).

There are also issues under §103, the main issues under §103 being:

whether or not claims 26 and 27 would have been obvious to a person of ordinary skill in the art at the time appellants' invention was made from a consideration of Graves in view of Horn et al USP 4,726,955 (hereinafter simply "Horn");

whether or not claims 1-5, 7, 13 and 14 would have been obvious from Lang in view of Brumlick; and

whether or not claims 1-14, 24-28 and 45 would have been obvious from Tonnuci in view of Dale et al, Journal of Food Science (hereinafter simply "Dale").

As regards the rejections under §103, there are of course a series of sub-issues as well, including among others whether or not the person of ordinary skill in the art would have attempted to combine the references as proposed; whether or not the references, even if combinable, would have led to the claimed subject matter; and whether or not a consideration of the prior art in combination would have provided any reasonable expectation of appellants' results.

Other sub-issues will become apparent from Appellants' argument section appearing below.

GROUPING OF CLAIMS

First, of course, all the claims that are subject to different rejections must be considered separately. Therefore, for this reason alone, applicants' claims do not all stand or fall together. Other reasons why they do not stand or fall together will be pointed out in the "Argument" section below.

However, for purposes of this appeal, and relative to the rejections based on the first paragraph of §112, claims 2-7 and 23 may be considered along with claim 1, and need not be considered separately; and claims 9-14 and 24-28

may be considered along with claim 8, and need not be considered separately.

As regards the rejection based on the second paragraph, it appears to be directed **only** against claim 5, and it therefore appears that only claim 5 needs to be considered relative to this rejection.

As regards the rejection under §102 based on Graves, the product claims and the method claims should be considered separately. Among the product claims 1-7, 14 and 23, claims 2, 3, 7 and 23 may be considered along with claim 1, and need not be considered separately; but claims 4, 5 and 14 should be considered separately. Among the method claims 8-13, 24, 25, 28 and 45, claims 9, 11 and 12 can be considered along with claim 8 and claims 25 and 28 can be considered along with claim 24; but all of the other claims should be considered separately.

As regards claims 14 and 41-43 which are rejected under §102 as anticipated by Tonnuci, claims 14, 41 and 42 may be considered together, but claim 43 should be considered separately.

As regards claims 1-3 and 5-7 which are rejected under §102 as anticipated by Brumlick, claims 2, 3, 6 and 7 may be considered along with claim 1 and need not be

considered separately, whereas claim 5 should be considered separately.

As regards the rejection under §102 of claims 1-3, 5, 6, 13 and 14 said to be anticipated by Szabo, claims 2, 3 and 6 can be considered along with claim 1 and need not be considered separately. Claims 5, 13 and 14 should be considered separately.

As regards claims 1-5 and 14 rejected under §102 as anticipated by Bradley, again claims 2, 3 and 14 may be considered along with claim 1, but claims 4 and 5 should be considered separately.

As regards claims 1-5, 7, 13 and 14 rejected under §102 as anticipated by Lang, again claims 2 and 3 may be considered along with claim 1 and need not be considered separately. Each of claims 4, 5, 7, 13 and 14 should be considered separately.

As regards the rejection of claims 26 and 27 under §103 as obvious from Graves in view of Horn, these claims may be considered together.

As regards the rejection under §103 of claims 1-5, 7, 13 and 14 as obvious from Lang in view of Brumlick, again claims 2 and 3 may be considered along with claim 1 and need not be considered separately. But claims 4, 5, 7, 13 and 14 should each be considered separately.

As regards the rejection of claims 1-14, 24-28 and 45 as obvious under §103 from Tonnuci in view of Dale, the product claims and the method claims should be considered separately. Among the product claims 1-7 and 14, claims 2, 3, 6 and 7 may be considered along with claim 1, and need not be considered separately; but claims 4, 5 and 14 should be considered separately. Among the method claims 8-13, 24, 25, 28 and 45, claims 9, 11 and 12 may be considered along with claim 8, and claims 25 and 28 can be considered along with claim 24, but the other claims should be considered separately.

Appellants make no admissions that any of the claims are or are not patentably distinct from one another.

THE DECLARATION

Along with the Reply filed June 10, 2003³, Appellants filed a Declaration in the name of the first named inventor and applicant, Dr. Dov Hartal. On August 1, 2003, the same day the final Action was issued, and of course before Appellants' receipt of the final Action, Appellants filed documentary evidence in support of Dr. Hartal's Declaration. The Declaration and supporting documentary evidence was submitted because of the Examiner's refusal to accept allegations of the Appellants, including statements made in

Appellants' specification⁴. Appellants will refer to the Declaration and the supporting documentary evidence at appropriate points in the "Argument" section of this Brief, below.

ARGUMENT

Appellants respectfully submit that Appellants' claims meet all the statutory requirements, including those of §§112, 102 and 103 for patentability, and that the examiner has not met his initial burden as required by MPEP 706.02(j).

I- Appellants' Claims Meet the "Description" Requirement of the First Paragraph of §112

Claim 1 of the present application calls for a coloring material in the red color range which "comprises from 500-3,000 ppm of said chromoplast particles encapsulating crystalline lycopene", the "said chromoplast particles" being recited as "particles separated from a fruit which contained them".

³ The Reply is misdated June 4, 2003.

⁴ Appellants wish to respectfully note the general rule that what an applicant states in his or her specification is to be accepted by the PTO in the absence of evidence or good reasoning to the contrary. Cases which support Appellants' position include *In re Costello*, 178, USPQ 290, 292; *Ex parte Johnson*, 40 USPQ 576; *In re Andrews*, 160 USPQ 360, 366; *Ex parte Leonard*, 187 USPQ 122, 123-124. The present Appellants submit and believe that there is no evidence or good reasoning which is contrary to what is stated in Appellants' specification as regards the state of the prior art, the problems which existed in the prior art, and the advantages achieved by the present invention.

The paragraph on page 9 of Appellants' specification, first two lines, states as follows:

Lycopene in the coloring material of the present invention is in the concentration range from 500-3,000 ppm, which is at least ten-fold the concentration of lycopene in whole native tomatoes, which is in the range of 50 to 100 ppm.

Claim 8, the first method claim recites that the process "is carried out under conditions providing said chromoplast particles containing crystalline lycopene in said solid material thereby obtaining a color concentrate comprising said color-imparting agent," and further recites that the resultant "coloring material comprises from 500 to 3,000 ppm of lycopene..." Claim 8 does not require any particular concentration of lycopene in the resultant color concentrate, but that it only be somewhere in the range of 500-3,000 ppm of lycopene.

Again, this is fully consistent with the description of the invention in Appellants' specification at the top of page 9.

The rejection is unjustified and should be reversed. Such is respectfully requested.

II- Applicants' Claims are Fully Enabled

The examiner says that Appellants' specification does not enable the person skilled in the art to extract the

chromoplasts from the fruit without causing substantial mechanical breakage or destruction of the chromoplasts. This is incorrect.

Appellants' specification states as follows at page 7, top paragraph, with particular emphasis on lines 8-10, as follows:

Upon breakage and fractionation of tomato fruit into soluble and insoluble fractions, the chromoplasts are found in the insoluble fraction in concentrated form. The intense red color of lycopene is absolutely dependent on its intact crystalline structure;... That is, the crystalline structure of lycopene is more readily preserved therein, and is not destroyed or otherwise changed as occurs [in the prior art] with rigorous extraction of the chromoplasts. (bracketed material added)

The present invention is therefore clearly indicated as being carried out without "rigorous extraction of the chromoplasts", thus preventing substantial destruction of the chromoplasts.

As pointed out in Appellants' specification, centrifugation is known in the art to be a gentle separation process, and this is confirmed in paragraph 2 of Dr. Hartal's declaration. Such separation is exactly what is disclosed in Appellants' specification (see page 11, lines 8 and 19, page 13, lines 5 and 13). This separation process is also shown in the examples, attention being invited to the fifth line of Example 1, the second line of Example 2 and the fourth line of

Example 3. That simple centrifugation works is shown by the results which the Appellants obtained.

Certainly those skilled in the present art would have no trouble practicing Appellants' invention based on their common knowledge coupled with Appellants' disclosure as noted above that the separation should be gentle in order to minimize breakage of the chromoplasts. Indeed, Appellants believe that there would be no experimentation necessary at all. However, if any experimentation were necessary, it would at most be routine experimentation which is well accepted to be permissible under 35 U.S.C. 112. Thus, Appellants respectfully submit that little or no experimentation would be necessary, taking into account the fact that centrifugation is known in the art to be gentle, coupled with Appellants' examples and the results obtained.

The product claims as represented by claim 1 do not require any particular process. Once the person skilled in the art reads Appellants' specification and learns that an objective is to minimize fracturing of the chromoplasts, such person skilled in the art will now how to proceed.

The process claims as represented by claim 8 specifically call for separating by centrifugation. The person skilled in the art, upon reading appellants'

specification, will know to carry out centrifugation in such a way as to minimize fracturing of the chromoplasts.

The examiner, in the final rejection in the top paragraph on page 3, refers to page 9 of paper 9 (presumably Appellants' Reply of March 30, 2001) as allegedly stating that Appellants' centrifugation is "not essentially different [than] those conventionally carried out in the tomato processing industry" (bracketed material of examiner). While Appellants are unable to find such quotation at page 9 or anywhere else, Appellants do agree that centrifugation is known in the prior art. But this is not the end of the matter, because centrifugation in the prior art is invariably carried out without regard to whether or not the chromoplasts are fractured; and, more importantly, tomato-based products in particular are always heated substantially in the prior art. Such heating, particularly when employed with mechanical separation, destroys the chromoplasts (see paragraph 4 of Dr. Hartal's declaration).

The rejection is unjustified and unsupported, and should be reversed. Such is respectfully requested.

III- Appellants' Claims Meet the Requirements of the Second Paragraph of §112

Appellants are puzzled by the rejection of claims 1-14, 23-28 and 41-44 under the second paragraph of §112, as

only claim 5 is criticized as being indefinite in the Final Action (middle paragraph on page 4). It therefore follows that the rejection does not apply at all, i.e. it totally without basis, with respect to claims 1-4, 6-14, 23-28 and 41-44.

As regards claim 5, appellants' specification states (second sentence of top paragraph on page 9) as follows:

The higher limit of the concentration range of the coloring material of the present invention may be achieved using as a starting material a tomato variety which is especially rich in lycopene.

These tomatoes are known. What an applicant states in his specification is to be accepted by the examiner in the absence of evidence or good reasoning to the contrary, noting the case law cited in footnote 4, *supra*. The examiner has no evidence or good reasoning to the contrary, but simply says that what is recited in claim 5, namely "a high lycopene-content tomato variety" cannot be ascertained by those skilled in the art, and therefore the claim is indefinite. But as the examiner has no evidence or good reasoning, he has not meet his burden.

If any evidence were needed, it can be found in Dr. Hartal's Declaration, noting paragraph 7 at the top of page 4 which states as follows:

7. High lycopene content tomatoes are well known. While conventional ripe tomatoes contain 60-100 ppm of lycopene, the high

lycopene content tomatoes contain a lycopene content of about 160 ppm or more.

To summarize, the rejection is based in speculation whereas Dr. Hartal's Declaration is based on his knowledge of the facts. The examiner has provided no evidence or good reasoning to the contrary.

The examiner's position seems to be that the mere inclusion of the word "high", regardless of the circumstances, renders a U.S. claim "indefinite" under the second paragraph of §112. But that is not correct. The Supreme Court of the United States, in a ruling which has not been overturned by any later Supreme Court decision or by statute, in the famous *Eibel* case, *Eibel Process v. Minnesota & Ontario Paper*, 261 US 45, approved the term "high".

Also please see *Charvat v. Commissioner*, 182 USPQ 77, 585, where "high concentration" was found to be acceptable. In *Ex parte Romentschuk*, 188 USPQ 542, the terminology "small amount" was found to be acceptable. The term "high" in Appellants' claim 5 is not indefinite, because it would be well understood by those skilled in the art upon reading Appellants' specification, again noting paragraph 7 of Dr. Hartal's Declaration.

As of June 3, 2003, the word "high" had appeared in the claims of 235,418 U.S. patents issued since 1976, showing that the term "high" is ubiquitous in U.S. patent claims.

Attention is respectfully invited to *Ex parte Brian et al*, 118 USPQ 242, 245 (1958) where the Board stated in part as follows:

..., Appellants have referred to numerous patents dealing with the subject matter involved in the present case, which have been allowed on the basis of claims [using particular] characteristics.... Since the claims under consideration are similar to those in the patents, we do not feel disposed to reject them and thus upset such a long established practice in the particular art under consideration. Accordingly, we will not sustain the rejection....

Accordingly, claim 5 is not indefinite simply because it includes the term "high".

Appellants respectfully request reversal of the rejection based on the second paragraph of 35 U.S.C. 112.

IV- Graves Does Not Anticipate Any of Claims 1-14, 23-25, 28 or 45

Graves, which is acknowledged prior art and is discussed in the top paragraph on page 4 of Appellants' specification, is antithetical to the present invention. In this regard, Graves states as follows at column 3, lines 16-19:

Disruption of the cell structure of the carotenoid source during separation generally inherently results in transfer of the carotenoid(s) in the carotenoid source from the pulp fraction to the liquid fraction.

This disruption of the cell structure, i.e. destruction of the chromoplast membrane, is exactly what Appellants wish to and have substantially avoided, and what gives Appellants' product improved resistance to oxidation and resistance to loss of the deep red color. This is clear from the language of claim 1, which states in part as follows:

A coloring material in the red color range
comprising,

chromoplasts particles encapsulating
crystalline lycopene..., ...

wherein the coloring material
comprises... **said chromoplast particles**
encapsulating crystalline lycopene, and....

If the cell structure of the carotenoid source is disrupted as required by Graves, then clearly Graves does not provide chromoplast particles encapsulating crystalline lycopene, a key feature of the present invention, and a feature called for in all of Appellants' claims.

Graves clearly does not disclose (and therefore does not anticipate) a coloring material of lycopene-containing chromoplast particles, let alone such a composition comprising 500-3,000 ppm thereof wherein the material has a soluble solids concentration below 5° Bx.

As regards Appellants' claim 4, Graves also does not show a coloring material which has been water washed.

As regards Appellants' claim 5, Graves does not show a coloring material which has been derived from a high lycopene-content tomato variety.

As regards claim 8, Graves does not show a process as recited, which

is carried out under conditions providing said chromoplast particles containing crystalline lycopene....

In addition, step (d) of claim 8 recites the following operation:

separating by centrifugation a fruit serum from a solid material thus obtained and **retaining said chromoplast particles with said solid material,....**

This is also is inconsistent with Graves which discloses **working with the liquid fraction**, contrary to the present invention, i.e. the Graves second step is

(ii) treating the carotenoid-containing **liquid** fraction with a carotenoid precipitation agent including calcium chloride, calcium hydroxide, calcium lactate or calcium gluconate, so as to fractionate the **liquid** fraction into a carotenoid-enriched solid precipitate portion and a carotenoid-depleted liquid portion,....
(emphasis added)

Then, as indicated above, Graves further teaches away from the present invention by emphasizing the necessity of disruption of the cell structure of the carotenoid source (column 3, lines 16-19). See paragraph (a) on page 4 of Dr. Hartal's declaration.

If there were any doubt, that doubt should be laid to rest by Dr. Hartal's statement in paragraph (a) on page 4 of his Declaration, as follows:

(a) As regards the Graves document, it is clear that Graves is working with the liquid fraction. Graves specifically refers to "cell disruption" and this certainly means of destruction of the chromoplast membrane.

The examiner has only unsupported speculation to the contrary, which is not even reasonable.

Claim 10 adds the operation of water washing the color concentrate, which is not disclosed by Graves.

Claim 11 adds the operation of processing the color concentrate to avoid microbial spoilage, and there is not such disclosure in Graves. Claim 12 adds to claim 10 the option of a variety of preservation techniques, none of which are disclosed by Graves.

Claim 13 is effectively a method of use claim. It calls for adding the coloring agent of claim 1 to another tomato product to provide a tomato product of constant color. There is not the remotest suggestion in Graves of any such method.

Claim 14 defines a tomato product which has been colored with the coloring material of claim 1. There is no such disclosure of any such product in Graves.

Claim 24 is an independent claim along the lines of dependent claim 13, but which requires the use of tomatoes comprising chromoplasts containing lycopene in the amount of at least 120 ppm. There is no such disclosure in Graves. Claim 24 further defines over Graves in the same way as does claim 8, and further in the same way as claim 12.

Claim 25 defines over Graves in the same as claim 24, and further requires an additional washing step of the color concentrate if the food product to which the color concentrate is added is not a tomato product, also not disclosed by Graves.

Claim 28 depends from claim 24 and thus defines over Graves for the same reason as claim 24, and further requires the additional step of subjecting the color concentrate to at least one preservation technique of septic packaging, canning, freezing or dehydrating.

Claim 45 is a Jepson form claim similar to claim 13, but additionally specifically reciting the steps of claim 8 as well as the step of claim 13. Thus, claim 45 defines over Graves for the same reasons as pointed out above with respect to claims 1, 8 and 13.

The present invention is clearly fundamentally different from Graves: in the present invention, after gentle separation of the solids from the liquid by centrifugation,

Appellants obtain the chromoplast encapsulated lycopene from the solid fraction, and avoid disruption of the chromoplast as much as is reasonably possible. Graves is totally antithetical to the present invention.

Graves does not anticipate any of Appellants' claims, and the rejection under §102 based on Graves should be reversed. Such is respectfully requested.

V- Claims 14 and 41-43 are Novel Over Tonnuci

Tonnuci involves a study of commercially processed tomato-based food products (last paragraph on first page). Table 2 on page 583 shows the lycopene content of various tomato based products including tomato soup, tomato juice and vegetable juice; and Table 3 on the following page shows the lycopene content of catsup, spaghetti sauce, tomato paste, tomato puree and tomato sauce. Tonnuci thus relates to commercial tomato-based products such as soups, canned tomatoes, ketchup, spaghetti sauce, tomato paste, tomato puree, tomato juice and tomato sauce.

The rejection from an earlier Office Action (incorporated by reference into the Final rejection) focuses

on Table 3 which shows that tomato paste⁵ has a lycopene content (according to the rejection) of around 550 ppm. But tomato paste has a Brix value of approximately 30° Bx (see paragraph 6 of Dr. Hartal's declaration), far more than what is permitted according to the present invention.

All of the Tonnuci products are commercial products taken so-called "off the shelf". All of these commercial products are subjected to substantial heat during their preparation, causing considerable deterioration of the chromoplasts.

Claim 14 calls for a tomato product colored with the color concentrate of claim 1. This requires, first, a tomato product, of which Tonnuci shows many. However, claim 14 then requires that such tomato product be modified by being colored with the material according to claim 1. As Tonnuci does not disclose the material of claim 1 or anything remotely similar, Tonnuci does not anticipate claim 14. The same applies to claims 41 and 42.

Claim 43 requires that product of claim 41 be subjected to water washing. There is no such disclosure in

⁵The earlier final Action, incorporated by reference into the last rejection, also states on page 14, paragraph 56 that it is "well known that tomato juices will have Brix values of around 5, even less than 5." Regardless, no tomato juice would correspond to Appellants' claims because the chromoplast particles will have largely been destroyed by heating to make the canned tomato juice safe, and tomato juice will not contain 500 to 3,000 ppm of chromoplast particles as claimed, i.e. tomato juice contains no more than about 100 ppm, again noting paragraph 5 of Dr. Hartal's declaration. Please also see the documentary evidence filed August 1, 2003, in support of Dr. Hartal's declaration.

Tonnuci, and therefore claim 43 defines over Tonnuci for this additional reason.

Therefore, the commercial products as disclosed by Tonnuci cannot meet any of Appellants' claims wherein the chromoplasts encapsulate the lycopene, it being understood that the chromoplasts in the present invention are largely or even substantially intact; and cannot meet any of claims 14 and 41-43 which require the aforementioned concentrate to be added to a food product, no such admixture being disclosed by Tonnuci.

The rejection under §102 based on Tonnuci should be reversed, and such is respectfully requested.

VI- Claims 1-3 and 5-7 are Novel Over Brumlick

Brumlick, similar to most of the other citations, is interested in a commercial way of making food products including tomato-based or tomato flavored foods or concentrates. In every case as shown in Fig. 1 and described at column 2, lines 57-61, the vegetable juice, separated from the vegetable solids "is passed through one or more filters in a filtering step 15 followed by **evaporating or distilling operations 16** in which a substantial amount of the liquid or water is removed to provide a thick, viscous residue 17." (emphasis added).

Here again, as in Graves discussed above, Brumlick is working with the liquid fraction (absolutely contrary to the present invention) rather than the solid fraction. Then, to make Brumlick even more distinct from the present invention, the liquid is subjected to high heat which would inevitably destroy any chromoplasts present in that fraction. Indeed, the resultant thick, viscous residue 17, obtained after distilling off the water, is then subjected to even more heat in a radiation step 21 "which is sufficient to toast the material...." (Column 3, line 4). Please again see the last sentence of paragraph 1 of Dr. Hartal's attached declaration which makes clear that such heating must be avoided to obtain Appellants' results. Item 4, two documents attached to the Submission of Documentary Evidence in Support of Dr. Hartal's declaration, also confirm the damaging effects of heat.

To briefly summarize, Brumlick involves distilling steps and toasting steps (e.g. Fig. 1; column 2, lines 57-61; column 3, line 4; and the examples), i.e. high heat, destructive of the chromoplast membrane.

As regards claim 5, Brumlick does not disclose the use of high lycopene-content tomatoes.

Clearly, Brumlick does not anticipate any of Appellants' claims 1-3 or 5-7, and the rejection should be reversed. Such is respectfully requested.

VII- Claims 1-3, 5, 6, 13 and 14 Define Novel Subject Matter
Over Szabo

Szabo relates to the manufacture of tomato puree. As indicated above, in the manufacture of such commercial products, the tomato material is inevitably heated to a relatively high temperature which inevitably results in the destruction of the chromoplasts.

Exactly what Szabo does is somewhat unclear⁶. However, it appears that after breaking, Szabo obtains a tomato juice (see Fig. 1). Such juice, containing tomato colloids having negative electric characteristics (column 1, lines 45 et seq.) is then subjected to coagulation, preferably using calcium ions.

Next, a "considerable parts of the serum can be decanted and evaporated." (column 2, lines 14-15). Presumably evaporation involves **substantial heat**. (Bradley says that Szabo "degrades the cellular structure of the tomato macerate.") Evaporation is also mentioned at column 2, lines 19-30, and it is unclear whether this is the same evaporation or a further evaporation. What is obtained eventually is a concentrated serum which smells of tomato (column 2, lines 37-38), clearly suggesting that the chromoplasts have been destroyed, which is inevitable in any event due to the

⁶ The initial burden is on the examiner. The rejection is based on speculation as to what Szabo did. It is simply not disclosed.

substantial heating applied. Also see column 3, lines 5-10 in this regard.

The resultant product of Szabo is a tomato puree which "has an attractive appearance, smells like tomato [and can be used to make "dishes"] which have taste and character similar to those made with the traditional tomato purees." In the present invention, the tomato smell and taste are largely eliminated (because the chromoplasts are maintained as claimed), and this proves that Szabo does not inherently produce Appellants' product. Neither the process nor the product of Szabo correspond to the claimed subject matter.

Claim 5 adds to claims 3 and 1 that the tomato is a high lycopene-content tomato variety, and there is no such disclosure in Szabo.

Szabo does not anticipate any Appellants' claims. The rejection based on Szabo should be reversed, and such is respectfully requested.

VIII- Claims 1-5 and 14 are Novel Over Bradley

As with most of the other references relied upon, Bradley also is concerned with the manufacture of a tomato based food product such as juice, soup, sauces, paste (column 5, lines 12-15). Bradley is particularly interested in a particular part of the overall process involving separating a tomato macerate to a reduced insoluble solids pulp fraction

and an insoluble solids-enhanced pulp fraction. At the very beginning, after chopping the fresh tomatoes, they "are heated to inactivate enzymes" (column 3, lines 6 and 7), and this will destroy chromoplasts. If the tomatoes are macerated using the hot-break method, they are heated to 60-100°C, preferably at least 85°C (column 3, lines 25-30).

Bradley appears to favor the hot-break⁷ procedure, and in this regard suggests higher temperatures for better consistencies, noting column 5, lines 7 and 8:

Generally higher break temperatures yield higher consistencies for both fractions.

In the illustrated embodiment, hot-breaking is disclosed, noting the hot-break tanks 110 and 120 (see column 8, lines 3 etc.). In the sole example (column 9), a hot-break tomato macerate is used.

As pointed out above, Bradley also discusses the aforementioned Szabo patent and basically confirms Appellants' position noting column 5, lines 44-50 as follows:

Secondly, the mechanical separation procedure of the prior art [Szabo (see col.5, ll. 19 and 20 of Bradley)], i.e. high speed centrifugal separation, unavoidably **degrades** the cellular structure of the tomato macerate,... This **degradation** unavoidably impairs the ultimate consistency obtained in subsequently obtained tomato products. (emphasis added)

⁷ But even the cold-break procedure normally involves substantial heating, noting the Lang reference discussed below.

While the separation practiced by Bradley is apparently less vigorous than that practiced by Szabo, Bradley explicitly does not avoid the use of heat. The "rough handling and heat" carried out and taught by Bradley "inevitably results in the destruction of chromoplasts and in oxidization of lycopene", noting paragraph (d) of the Hartal Declaration, which states as follows:

(d) The Bradley document subjects the tomato parts to rough handling and heat, and this inevitably results in the destruction of the chromoplasts and in oxidation of lycopene. This document states that the chopped tomatoes "are heated to inactivate enzymes", and this will inevitably destroy chromoplasts.

In the end, Bradley does not and cannot obtain what is claimed in claim 1, namely

A coloring material in the red color range,
comprising
chromoplast particles encapsulating crystalline
lycopene as the color-imparting agent,
said chromoplast particles being particles separated
from a fruit which contained them,
wherein the coloring material comprises from 500 to
3000 ppm of said chromoplast particles encapsulating
crystalline lycopene, and
wherein the coloring material has a soluble solids
concentration below 5° Bx.

As regards claim 4, Bradley does not disclose any coloring material which has been water-washed.

With regard to claim 5, Bradley does not disclose starting with a high lycopene-content tomato variety.

Bradley does not anticipate any of Appellants' claims. The rejection should be reversed and such is respectfully requested.

IX- None of Appellants' Claims 1-5, 7, 13 or 14 is Anticipated

By Lang

Lang suffers from many of the deficiencies of the references already discussed above in the manufacture of a tomato based product for storage and consumption. Heating is unquestionably an aspect of the Lang process; and, interestingly, Lang defines even the "cold break" method as involving temperatures of 70-75°C (column 2, lines 3-9) with tomatoes processed according to the "hot break" method being heated to 95-100°C.

In Lang, the tomato slices are heated to a temperature of at least 65°C (abstract line 5; column 2, lines 28-31), and more preferably at least 75°C (column 2, lines 64). Apparently, the temperature must be sufficiently high to denature the polygalactonase in the tomatoes (column 2, lines 3 and 4; lines 67 and 68). In the illustrated embodiment, the tomato serum is heated to approximately 95°C (column 4, lines 24-25). As pointed out above, the processing including such heating inevitably ruptures the chromoplast walls. See

paragraph (f) of the Hartal Declaration, which states as follows:

(f) The Lang citation mentions treatment of tomato by either a "cold break" method or "hot break" method. The cold break method involves temperatures of 65-70°C and the hot break method involves temperatures of at least 95°C. The temperature must be sufficiently high, according to the Lang citation, to deactivate the pectolytic enzymes in the tomatoes. Following what Lang says to do will result in destruction of the chromoplasts.

Dr. Hartal, an expert in this art, is entitled to provide statements of fact based on his knowledge and experience.

As with the other prior art documents discussed above, Lang does not and cannot obtain the claimed subject matter including chromoplast particles encapsulating crystalline lycopene, wherein the coloring material comprises from 500-3,000 ppm of the chromoplast particles, and wherein the coloring material has a soluble solids concentration below 5 degrees Brix, as claimed.

There is no "reasonable certainty" or inevitably that Lang inherently produces the claimed subject matter⁸, and

⁸ The basis of most of the prior art rejections relied upon by the examiner is somewhat unclear to Appellants due to the examiner in each Office Action referring to the "reasons set forth in the last Office Action". Appellants are thus unsure whether or not the examiner is taking the position that Lang (and /or other citations relied upon) inherently provide the subject matter of claim 1. But there is no inherency under the law, unless the inherency is "certain", noting *Ex parte Cyba*, 155 USPQ 756, 757 (1967), or is "inevitable", noting *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981), or is reasonably certain, noting *In re Brink*, 164 USPQ 247, 249.

indeed it is clear that Lang does not and cannot do so. Neither Lang nor any of the other prior art relied upon inherently provides appellants' claimed subject matter.

Claim 4 adds to claim 1 that the coloring material has been water-washed, and this feature is not disclosed by Lang

Claim 5 adds to claims 3 and 1 that the tomato is a high lycopene-content tomato variety, and this is another feature not disclosed by Lang.

Claim 13 calls for a method by which a tomato product is provided with a consistent color, "comprising adding to said tomato product a coloring effective amount of a coloring material as defined in claim 1." Lang shows no such method.

Claim 14 calls for a tomato product which has been colored with the coloring agent of claim 1. Lang discloses no such product.

Lang does not anticipate any of Appellants' claims. The rejection based on Lang should be reversed, and such is respectfully requested.

X- Claims 26 and 27 Define Non-Obvious Subject matter over Graves In View of Horn

Claim 26 depends from and incorporates the subject matter of claim 24. Claim 27 depends from claim 26 and

incorporates the subject matter of claim 26 (including claim 24).

Graves has been discussed above where it has been pointed out how Appellants' claims define over Graves. Horn has not been cited to make up for what Applicants have pointed out that Graves does not have. Therefore, even if the combination were obvious (not conceded by Appellants), the resultant combination would not correspond to what is claimed.

The statement of this rejection appears to go back to the Office Action mailed March 25, 1998, in application 08/507,632, at pages 6 and 7. As understood, Horn is relied upon to "teach the prior art use of a colloid mill to reduce the size of carotenoids to increase their solubility". The rejection states that it "would have been obvious to those of ordinary skill in the art to use the colloid mill of the prior art, as taught by Horn et al, in the process of Graves et al for its intended and well taught use." However, this would in no way lead to the present invention, even if such a combination were obvious. The addition of Horn to Graves does not do away with the teaching of Graves to disrupt the cell structure of the carotenoid.

Nowhere in the prior art is it taught that one should try to not disrupt the chromoplasts membrane, which is a key aspect of appellants' invention. Accordingly, even if

the combination were obvious, it would not lead to the present invention.

Claims 26 and 27 would not have been obvious to the person of ordinary skill in the art at the time the present invention was made. Appellants respectfully request reversal of this rejection.

XI- Claims 1-5, 7, 13 and 14 Would Not Have Been Obvious From A Consideration Of Lang In View Of Brumlick

The statement of this rejection appears to go back to pages 8 and 9 of the Office Action of August 20, 1996, in application 08/507,632. Both Lang and Brumlick have been discussed above; appellants believe they are substantially cumulative. Even if it were obvious to combine them as proposed, the results of such a combination would not correspond to appellants' claimed subject matter.

The ways in which the present invention as called for in claim 1 defines over Lang have been discussed above. Brumlick does not make up for these differences and has not been cited to do so. Therefore, even if the proposed combination were obvious, not admitted by Appellants, the resultant combination would not correspond to the subject matter of claim 1 or any of the claims dependent thereon.

Claim 4 adds to claim 1 the feature of the coloring material having been water-washed, and this is not disclosed

by either Lang or Brumlick, and therefore no possible combination of the two can meet this additional feature.

Claim 5 adds to claim 3, including claim 1, that the tomato starting material is "a high lycopene-content tomato variety." This added feature is not shown by either Lang or Brumlick, and therefore cannot be achieved by any combination of these citations, even if obvious.

None of claims 1-5, 7, 13 or 14 would have been obvious to a person of ordinary skill in the art at the time Appellants' invention was made from a consideration of Lang in view of Brumlick. Accordingly, Appellants respectfully request reversal of this rejection.

XII- Claims 1-14, 24-28 And 45 Define Non-Obvious Subject Matter Over Tonnuci In View Of Dale

The statement of this rejection appears to go back to pages 6 and 7 of the Office Action of April 7, 1997, in application 08/507,632. Both Tonnuci and Dale are directed to the same general subject matter, i.e. tomato concentrates of one type or another. They both lack key features of the present invention as pointed out above, and any possible combination of the two, even if obvious, could not possibly result in appellants' claimed subject matter.

Tonnuci has been discussed above. Dale discloses heating, which inevitably destroys the chromoplasts.

As is clear from the abstract of Dale, the Dale "process alternatives" all involve substantial heating. On the first page, second column under the heading "MATERIALS & METHODS", it is indicated that the chopped tomatoes were heated to 90 C. Such a "hot break" is called for in all five systems of Dale as shown on the following page, and this is followed by more heat, i.e. a triple effect evaporation. All this use of heat is contrary to the present invention, as such heat "will inherently and inevitably result in a deterioration of the chromoplasts" noting paragraph (e) of the attached Hartal declaration.

In the first full paragraph on page 8 of the most recent Final Action, the examiner says that the claims do not exclude heating. However, the claims recite a resultant product which cannot be obtained by the process of Dale.

As noted above, both Tonnuci and Dale relate to commercial tomato based products which have been subjected to substantial heat during their manufacture. No possible combination of these documents, even if obvious, could result in Appellants' color concentrate of claims 1-5 or 7, or in Appellants' process for making such a coloring material as called for in Appellants' claims 8-12, or in Appellants' method of claim 13 whereby "a coloring effective amount of a coloring material as defined in claim 1" is added to a tomato

product to provide that tomato product with a constant color, or the tomato product of claim 14 which is a tomato product colored with a material according to claim 1, or the process for coloring food products as called for in claims 24-28, or the method of claim 45.

The various subsidiary claims have been individually discussed in conjunction with other rejections. To avoid additional prolixity, appellants respectfully repeat by reference the commentary made above with regard to the various subsidiary claims, and respectfully note that features set forth in the dependent portions of subsidiary claims 4, 5, 10 and 25-27 would not be reached by any proposed combination of Tonnuci in view of Dale.

Appellants' claims 1-14, 24-28 and 45 define non-obvious subject matter over Tonnuci in view of Dale. Appellants respectfully request reversal of the rejection.

XIII- Appellants Rebuttal To The Examiner's "Response To Arguments"

Except for the introduction which appears at the bottom of page 6, the examiner's "Response to Arguments" appear at pages 7 and 8 of the final Action of August 1, 2003, Paper no. 28.

In the top paragraph on page 7, the Examiner tries to explain why he believes Tonnuci anticipate claims 14 and

41-43. Unfortunately, this explanation makes no sense to Appellants.

Tonnuci provides tables of different commercial products based on tomatoes. Except for tomato juice, all such products have a soluble solids concentration well above 5° Brix (Bx). Therefore, none of these products anticipate any of Appellant's claims. While tomato juice may indeed have a soluble solids concentrate below 5° Brix, it does not contain chromoplast particles encapsulating crystalline lycopene in an amount falling somewhere in the range of 500-3,000 ppm. Please see paragraphs 5 and 6 of Dr. Hartal's Declaration which confirm these facts, as well as the documentary evidence filed August 1, 2003.

Next, the examiner states that Graves anticipates, even though Graves works with the liquid fraction, because the instant claims are not restricted to non-liquid fractions. But, as pointed out above, claim 8 explicitly recites "retaining said chromoplast particles **with said solid material**" clearly contrary to Grave.

As regards Appellants' product claims including claims 1-7, 14 and 23, they all call for chromoplast particles encapsulating crystalline lycopene, subject matter which is not possible according to Graves which, as noted above, emphasizes the necessity of disruption of the cell structure.

The Examiner brushes aside Dr. Hartal's Declaration as being "not based on any evidence and therefore is not found persuasive." But Dr. Hartal's Declaration is evidence. The Examiner seems to erroneously believe that only Declarations which provide comparative results are entitled to any weight, but this is not correct, noting for example *In re Alton*, 37 USPQ2d 1578, 1583-84 (Fed Cir 1996). Dr. Hartal is an expert in this art, and even his opinions are entitled to substantial weight. The statements which the Examiner brushes aside are more than opinions, i.e. they are statements of fact based on Dr. Hartal's experience.

The Examiner says that Appellants disrupt cells, and "it is not seen that Graves does anything differently." With respect, appellants do not see how such a statement can be reasonably made in view of the fact that appellants do everything they can to not disrupt cells, whereas Graves emphasizes necessity of the disruption of cells.

Respectfully, the Examiner's position is akin to saying that night and day are equivalent because the full moon reflects sunlight. The Examiner's position is simply unreasonably.

Next, the Examiner refers to column 4, lines 51-56, of Graves and quotes therefrom "separation of carotenoid-enriched solid precipitate portion from the carotenoid-depleted liquid portion may be achieved by any conventional

method, including centrifugation...." But this quotation is taken out of context. The immediately preceding paragraphs relate to the treatment of the **liquid fraction**, especially of carrot juice. Thus, Graves is discussing further treatment of the **liquid fraction** of carrot juice. Graves states as follows commencing at column 4, line 37:

It is believed that optimal fractionation may also be obtained by treating the **liquid fraction** with one of the listed carotenoid precipitation agents....

Referring to FIG. 4 and Table Four, the pH of the liquid fraction can affect the rate of separation and overall separation efficiency.... Carrot juice having pH adjusted with NaOH as necessary... appears to provide the most complete separation (clearer liquid fraction).... (emphasis added)

So what Graves is disclosing is a further treatment of the liquid fraction, not the solid fraction as in the present invention.

As regards Brumlick, the Examiner states that "the solid material removed in the Brumlick process will contain the lycopene." But Brumlick does not disclose what is done with the solid fraction. Appellants submit that a rejection cannot be based on what Brumlick does not disclose.

With respect to Szabo, the Examiner states that only the serum is taught to have the flavor and aroma of tomatoes. However, Szabo discloses that the "tomato concentrate,

produced according to our method has generally a red colour, ... an attractive appearance, smells like tomato." (Column 3, second paragraph) This is contrary to the present invention.

As regards the combination of Bradley and Lang, it has already been pointed out above that even the cold-break method involves substantial heating according to the prior art.

The Examiner says that the obviousness rejections "meet all of the limitations of the claims and therefore a *prima facie* case of obviousness exists." Appellants have pointed out above that this is not correct.

CONCLUSION

The initial burden is on the Examiner, and the Examiner has not met his burden.

The present invention constitutes an improvement because the lycopene product produced, the subject matter of claim 1, is largely protected from oxidation by the chromoplast shells or capsules, only a small fraction of which are broken (page 7, lines 10-12). Because of the retention of the chromoplast capsule or shell, with the lycopene crystals therewithin, color intensity is maintained due to decreased oxidation.

The present composition is novel and unobvious in that it has both, i.e. in combination, a very low Brix with a very high lycopene content. Commercial tomato based products, with the exception of tomato juice, have a very high Brix; tomato juice, while having a relatively low Brix (about 4.8 - 5.2), also has a much lower lycopene content, i.e. about 60 ppm, and no higher than 100 ppm, compared to the composition of the present invention (see paragraph 5 of Dr. Hartal's declaration).

In the manufacture of tomato based products, the tomato is usually subjected to two unit operations which cause extensive damage to the chromoplasts, these two operations being (1) the application of damaging heat, and (2) the application of intense mechanical activity (see paragraph 4 of Dr. Hartal's declaration). Maintaining a high percentage of intact chromoplasts according to the present invention is essential and is accomplished by avoiding or minimizing these unit operations (see paragraph 1 of Dr. Hartal's declaration). Thus, in accordance with the present invention, the solids are separated from the liquid simply by (gentle) centrifugation (see paragraph 2 of the Hartal declaration).

None of the references even hint at the present invention. Appellants have shown that heat is invariably used in the manufacture of tomato based food products, and that

heat disrupts the chromoplast shell exposing the crystalline lycopene to easy degradation. This is confirmed as factual in Dr. Hartal's declaration. The present invention has solved problems which existed in the prior art, thereby solving a long felt need, and defines novel and unobvious subject matter warranting allowance.

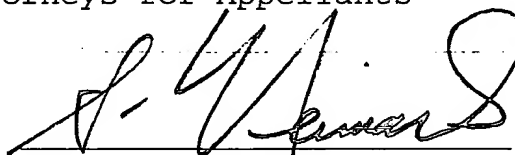
Appellants' claims meet the requirements of §112, define novel and unobvious subject matter under Sections 102 and 103, and should be allowed.

Appellants respectfully repeat that the Examiner has not met his burden. The rejections should therefore be reversed, and such is respectfully prayed.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Appellants

By



Sheridan Neimark
Registration No. 20,520

SN:jaa
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\M\MAKH\Hartel1B\Pto\Brief 29De03.doc

APPENDIX

1. A coloring material in the red color range comprising,
chromoplast particles encapsulating crystalline lycopene as the color-imparting agent,
said chromoplast particles being particles separated from a fruit which contained them,
wherein the coloring material comprises from 500 to 3000 ppm of said chromoplast particles encapsulating crystalline lycopene, and
wherein the coloring material has a soluble solids concentration below 5° Bx.
2. A coloring material according to claim 1, comprising as the color-imparting agent, chromoplast particles comprising crystalline lycopene, and further comprising color-neutral substances wherein the coloring material comprises from 500 to 3000 ppm of lycopene.
3. A coloring material according to claim 1, wherein the chromoplasts are derived from tomatoes.
4. A coloring material according to claim 1, which has been water-washed.

5. A coloring material according to claim 3, wherein the tomato is a high lycopene-content tomato variety.

6. A coloring material according to claim 1, in a dehydrated form.

7. A coloring material according to claim 1, in frozen form.

8. A process for preparing a coloring material comprising as a color-imparting agent chromoplast particles containing crystalline lycopene, comprising:

a) selecting and pre-treating a lycopene-containing fruit by cleaning it;

b) breaking the fruit;

c) screening out solid components above a predetermined dimension; and

d) separating by centrifugation a fruit serum from a solid material thus obtained and retaining said chromoplast particles with said solid material,

wherein said process is carried out under conditions providing said chromoplast particles containing crystalline lycopene in said solid material thereby obtaining a color concentrate comprising said color-imparting agent,

wherein the coloring material comprises from 500 to 3000 ppm of lycopene and wherein the coloring material has a soluble solids concentration below 5° Bx.

9. A process according to claim 8, wherein the fruit is tomato.

10. A process according to claim 8, further comprising water-washing the color concentrate.

11. A process according to claim 8, further comprising processing the color concentrate to avoid microbial spoilage.

12. A process according to claim 10, comprising at least one preservation technique selected from the group consisting of aseptic packaging, freezing, canning and dehydrating, optionally with the addition of a food preservative.

13. A method for producing a tomato product of constant color, comprising adding to the said tomato product a coloring effective amount of a coloring material as defined in claim 1.

14. A tomato product colored with a material according to claim 1.

23. A coloring material according to claim 1, wherein the coloring material comprises at least 1000 ppm of lycopene.

24. A process for coloring a food product which comprises:

a) cleaning and breaking tomatoes which comprise chromoplasts containing lycopene in the amount of at least 120 ppm;

b) screening out solid components therefrom of a predetermined size; and

c) separating a serum from a screened tomato solid material by centrifugation and retaining said chromoplasts with said tomato solid material,

wherein said process is carried out under conditions providing said chromoplast particles containing crystalline lycopene in said tomato solid material,

thereby to obtain a color concentrate comprising said chromoplasts containing crystalline lycopene in a concentration from 500 to 3000 ppm, and

d) introducing said concentrate into said food product.

25. A process according to Claim 24 wherein unless said products are not tomato products, further comprising washing the color concentrate.

26. A process according to claim 24 which comprises subjecting the color concentrate to size reduction.

27. A process according to claim 26, wherein the size reduction is carried out by processing the color concentrate in a colloid mill or microcutter.

28. A process according to claim 24 further comprising processing the color concentrate prior to using it as a coloring material by subjecting it to one or more of the following preservation techniques: aseptic packaging, canning, freezing or dehydrating.

41. In a food product or a health-promoting and health-maintaining consumable product comprising a lycopene additive of lycopene molecules as a food colorant or as a nutraceutical, the improvement wherein

said lycopene molecules are in crystalline form encapsulated in chromoplasts,

said chromoplasts are particles separated from a fruit which contained them,

the lycopene additive comprising from 500 to 3,000 ppm of said chromoplasts encapsulating said lycopene molecules, and

wherein said lycopene additive has a soluble solids concentration below 5° Bx.

42. The food product or health-promoting and health-maintaining consumable product of claim 41, wherein said chromoplasts are derived from tomatoes.

43. The food product or health-promoting and health-maintaining consumable product of claim 41, wherein said chromoplasts have been water-washed to remove flavors.--

45. In a method for coloring a food product or a health-promoting and health-maintaining consumable product, comprising adding a lycopene additive as a red food colorant to said food product or health-promoting and health-maintaining consumable product, the improvement wherein:

said lycopene additive comprises chromoplast particles encapsulating crystalline lycopene,

said chromoplast particles are particles separated from a fruit which contained them,

the lycopene additive comprises from 500 to 3,000 ppm of said chromoplasts particles encapsulating crystalline lycopene, and

the lycopene additive has a soluble solids
concentration below 5° Bx.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In Re Application of: Dov HARTAL et al
Application No.: 09/449,093
Filed: November 224, 1999
For: NATURAL COLORING PRODUCTS



Art Unit: 1761
Examiner: C.E. SHERRER
Arlington, VA
Atty.'s Docket: HARTAL=1B
Date: DECEMBER 29, 2003
Confirmation No.: 5856

Customer Window, Mail Stop Appeal Brief - Patents
THE COMMISSIONER OF PATENTS AND TRADEMARKS
Arlington, VA. 22202

Sir:

Transmitted herewith is a [X] BRIEF ON BEHALF OF APPELLANTS in the above-identified application.

[] Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted

[] A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.

[XX] Fee for Filing a Brief in Support of an Appeal \$330.00

The fee has been calculated as shown below:

	(Col. 1)		(Col. 2)	(Col. 3)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA EQUALS
TOTAL	* 25	MINUS	** 20	0
INDEP.	*	MINUS	*** 3	0
FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				

ADDITIONAL FEE TOTAL

SMALL ENTITY		
RATE	ADDITIONAL FEE	
x 9	\$	
x 43	\$	
+ 145	\$	
ADDITIONAL FEE TOTAL		\$

OTHER THAN SMALL ENTITY		
RATE	ADDITIONAL FEE	
x 18	\$	
x 86	\$	
+ 290	\$	
TOTAL		\$

- * If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.
- ** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 20, write "20" in this space.
- *** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment of the number of claims originally filed.

[XX] Conditional Petition for Extension of Time

If any extension of time for a response is required, applicant requests that this be considered a petition therefor.

[] It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

Small Entity
Response Filed Within
[] First - \$ 55.00
[] Second - \$ 210.00
[] Third - \$ 475.00
[] Fourth - \$ 740.00
Month After Time Period Set

Other Than Small Entity
Response Filed Within
[] First - \$ 110.00
[] Second - \$ 420.00
[] Third - \$ 950.00
[] Fourth - \$ 1480.00
Month After Time Period Set

[] Less fees (\$) already paid for month(s) extension of time on .

[XX] Credit Card Payment Form, PTO-2038, is attached, authorizing payment in the amount of \$330.00.

[XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR §1.16 and all patent processing fees under 37 CFR §1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR §1.18.

Facsimile: (202) 737-3528
Telephone: (202) 628-5197

BROWDY AND NEIMARK
Attorneys for Applicant(s)

By:
Sheridan Neimark
Registration No. 20,528